Hoffmann-La Roche's Cover-up of Accutane

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"Those who cannot remember the past are condemned to repeat it"
-George Santayana *The Life of Reason*

"Chronic cellular dehydration painfully and prematurely kills"
-F. Batmanghelidj, M.D. *Your body's Many Cries For Water*

"We cannot allow the drug manufacturer and the FDA to continue to turn a blind eye to the lives lost, families devastated and dreams dashed by an acne drug. The American people, our children, are not collateral damage in the scheme of corporate profits! Accutane is a powerful drug that can cause serious physical harm and death. With a drug like this on the market, it needs to be carefully tracked and monitored to reduce the exposures to the drug's harmful side effects. Unfortunately, we can't seem to rely on the FDA and the drug's manufacturer to do the right thing and implement such a plan."
-Michigan Congressman Bart Stupak

"An ongoing human horror story surrounds Accutane, the vitamin A drug used to treat acne. An untold number of Accutane users face life-long chronic side effects, and doctors offer no solutions to these problems. But there is hope. Effective natural remedies for acne would eliminate the appalling side effects of Accutane."
- Bill Sardi, investigative health journalist

"I've always tried to explain it as controlled vitamin A poisoning, as the potential side effects are similar to those that would occur if you took far too much oral vitamin A."
-Dermadoctor.com

"Skin coming off whole body"
-Arctic explorer Sir Douglas Mawson, January, 1913

"We simply assume, that the doctors have personal responsibility. They are specialists, who have the information either in their head or they know where to find it."
-Andres Schneider, Swissmedic

"Micheal Benz was a 31 year old fire fighter who never had acne but was prescribed Accutane. A tri-athlete, Michael cried out for help from his physician and was told to come back on Monday. Micheal Benz drowned himself by weighting his body down with weight lifting plates. The investigation into his death showed that he had logged onto an Accutane website the

weekend he died. As a fire fighter and an EMT, Michael Benz must have had some idea what was happening to him. Still, he could not resist the sudden urge to take his own life."

-United States Congress, *Supplemental Review of Accutane Safety Issues*

"The interesting thing about this drug it's that it was never intended for something like clearing up pimples. This was a drug that was intended for chemotherapy. Roche could not make enough money with it just with chemotherapy, so they said: Let's expand it. Let's sell it to more people. And they ended up selling it to people with acne. If you, today, were to ask Roche: Explain to me what is the mechanism, the bio mechanism of this drug. You know what? They wouldn't be able to tell you. They don't know. This drug has been on the market since 1982 and they have not spent one dime, not one single dime, trying to figure out how it works, how it goes about causing these side effects. You have 152, about 152 side effects. People would never make the choice to use this drug. Never. Once they understand how dangerous it is, there's no logic, there's no reasoning person that would say: I'm going to take Accutane to clear up pimples."

-Mike Papantonio, pharmaceutical litigation attorney

"Sale of Accutane on the Internet should be immediately prohibited. Independent studies urgently need to be carried out to establish exactly the mechanism by which this drug causes so many side effects. An appropriate medical treatment, this is probably the most important, must be devised to counteract the side effects and to provide treatment for the tens of thousands, if not hundreds of thousands, of people who have suffered severe side effects from this drug."

-Liam Grant, Ro/Accutane Action Group chairman

"Retinoic acid (active form of Accutane) induces differentiation and reduces proliferation of stem and progenitor cells. It works on acne by inducing similar events in basal sebocytes. These same actions also lead to 13-cis-retinoic's (Accutane's) side effects, and these are directed towards proliferating cells in the adult such as in the skin, gut and bone. A wide ranging effect of retinoic acid is to inhibit proliferation in dividing cells, and this accounts for its frequent consideration as an anti-cancer agent."

-James Crandall, Ph.D. UMASS Medical School Neuroscientist

"I believe I have discovered the elusive mechanism of action, which is down-regulation of the telomerase enzyme leading to telomere shortening, growth arrest and cell death. In other words the more Accutane you take, the more it increases your cellular turnover rate, driving the rapidly multiplying cells in your body toward their Hayflick Limit."

-Nathan Carr

"While there are many drugs that interfere with one or more aspects of sexuality while the user is taking them, with one exception all of these problems resolve once the drug is discontinued. The only drug that can permanently affect libido and sexual pleasure in some people is Accutane."

-Kevin Pezzi, M.D. *The Science of Sex*

"After years of denials, Roche will at last be forced to accept responsibility for its actions and the horrible illness its drug has burdened me with. While I am pleased with the jury's verdict, it's too bad that Roche can't give me my life back."

-Jordan Speisman

If you were to ask random people what they know about Hoffmann-La Roche's acne drug Accutane, 80 % of them will have never heard of it, and the other 20 % will probably say "yeah isn't that the acne medication that causes birth defects and psychiatric side effects?" These dangers are significant, but there's definitely much more to Accutane's rap sheet than just the birth defects and psychiatric side effects. A quick glance over the Physician's Desk Reference, some websites, and its recent medication guide reveals that Accutane owns one of the most extensive and hazardous side effect profiles of any drug ever approved by the FDA. This drug is not being used by a limited number of patients with a life-threatening medical condition. After 25 years it's still being handed out to thousands of healthy teenagers and young adults with a benign harmless condition almost everybody acquires at some point early in their lives, mild to moderate acne. Evidence has accumulated that Roche knew about many severe side effects before Accutane was released onto the market in 1982, but it is only recently (2001) that the FDA has forced them to create warning labels that accurately list these side effects. These disclosures arrived too late for thousands of former Accutane users who are only now discovering that the drug they trusted to help them overcome acne was affecting them in dangerous ways. Very recently, some doctors are still withholding crucial information by not giving their patients the medication guide or having them sign the informed consent forms, but even these documents don't list everything.

Since the information has managed to be suppressed so effectively, nobody knows the full story behind this unique drug and what is currently happening with it, so I've created this comprehensive report to blow the whistle because the time is now and long overdue. Accutane is a toxic drug that has proven to be a massive public health threat. I believe I have discovered Accutane's mechanism of action and later I will lay my evidence on the table for everyone to see. I've provided scientific studies to validate my hypothesis and I've used analogies and clear-cut language to make the complex biology easy to understand. Reputable physicians have told me that it sounds extremely promising as an explanation for the mechanism of action. Unless somebody comes along and stops them, history reveals that Roche and certain dermatology organizations will continue doing everything in their power to ensure Accutane stays on the market and continue to needlessly poison the health of many teenagers and young adults with mild to moderate acne. But I've put together the pieces of the puzzle and it is highly unlikely Roche will be able to keep Accutane on the market after my report gets widely distributed out into the open and the truth is finally brought to the surface. Many misinformed people, including some dermatologists, make statements about Accutane that have absolutely no validity whatsoever and they talk about it like it's over-the-counter cough syrup. It's not. It's a very dangerous and powerful chemotherapy drug that causes a long list of unpredictable serious side effects and is only supposed to be prescribed to the small minority of individuals with severe cystic acne all over their face and body. Somebody needed cut through all the BS that's constantly being promoted about Accutane being a safe miracle wonder drug, by presenting the facts, and that somebody turned out to be me. If you are a teenager with any type of persistent acne problem, don't let your vanity cloud your rationality. There's a trap waiting for you in the dermatologist's office. Let's learn more about it.

Today, anybody that is scientifically savvy and abreast about Accutane knows it decreases cellular proliferation everywhere across the board in the entire body; the skin, bone, digestive

system, mucous membranes, areas of the brain, and cancer, which is why it is used in chemotherapy, but up until now, no one supposedly knows exactly how it causes reduced cell division. All throughout the history of Accutane, Hoffmann-La Roche Pharmaceuticals has continued to use the lame excuse in the Physician's Desk Reference that "the exact mechanism of action is unknown" which is their way of copping out by stating that they don't understand how the drug works to reduce acne or how it causes side effects. Liam Grant, the chairperson of the Ro/Accutane Action Group, www.accutaneaction.com located overseas in the UK and Ireland, explained Roche's deceptive tactics very well at the FDA Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee held on September 19th, 2000.

"Roche have stated publicly for the past 17 years in every country -- because we followed the PR statements from Roche and they're all the same, and they haven't changed, by the way, since 1983 -- we do not know the mechanism by which this drug works. Therefore, there's no proof that Accutane causes depression or psychiatric disorders. And they have no shortage of medical people and others who will go up with this statement. So, here we have a product. We know it causes the side effects, but why do they cause them? Well, that's not our problem. We don't know how it works. Therefore, don't ask me about the psychiatric side effects and don't ask me about all the many, many, many physical side effects. The Ro/Accutane Action Group as an organization now have to go out and are now spending our money because we know, of course, that the mechanism can be determined."

http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3639t2.rtf

As Liam Grant just said, the mechanism of action can be determined. Roche has possessed this technological capability for quite a long time, and it is entirely possible they already know the mechanism but they just aren't telling anybody because doing so would incriminate them. A few organizations besides Roche have the technology needed to decipher Accutane's mechanism of action such as the Life Extension Foundation in Ft. Lauderdale, FL and the Linus Pauling Institute at Oregon State University. But their expertise might not be needed because I believe I have already discovered the mechanism of action. The smoking gun was published way back in 2001, and then buried away in the chemotherapy research archives, which is where I found it six years later and connected the dots. But we're talking about an acne medication, so why was I searching through chemotherapy research for clues on how Accutane works? Because Accutane is not technically an acne medication. Very few people know this. It was originally developed to be a chemotherapy drug and is still used as chemotherapy today for various types of cancers. It has powerful cellular proliferation reducing effects throughout the entire body, and acne reducing skin dryness happens to be one of its side effects. While clinical trials were being conducted in the 1970's, the researchers noticed that their cancer patients were having their acne cleared up during their chemotherapy. To make a long story short, this is when all logic and common sense got thrown out the window and Accutane slowly became known as a popular treatment for acne, not chemotherapy. At least the oncologists know what they're dealing with and counsel their patients thoroughly about the severe side effects when prescribing Accutane and other retinoid drugs for cancer. The American Academy of Dermatology on the other hand took the reckless approach when they decided that we don't know how this toxic chemotherapy drug works to reduce acne but we'll go ahead and dish it out to millions of healthy young people anyway.

During my in-depth investigation to expose the truth about Accutane, I was hard pressed to find any genuine good news associated with it. The only two benefits of this drug are that it fights the growth of cancer and it's effective at clearing up the most severe forms of cystic acne, the kind of acne so severe it leaves pot holes in the skin all across the body. For these people who represent a small percentage of everyone with acne, Accutane can work well and produce a favorable outcome when it's used properly in low dosages. But on the other end of the spectrum in terms of mild to moderate acne, which 90% of all Accutane prescriptions are given for, it's difficult to applaud the positive acne clearing aspects of Accutane when the drug is in actuality just plain pure poison that causes side effects in 100 % of everyone who takes it. Everybody gets dry/chapped/fissuring lips while on it which is a clear sign of vitamin A toxicity.

To all the teenagers and young adults reading this, remember that a little imperfection is just a part of being human. If you have a few acne spots on your body, who cares? This sort of thing tends to happen to the majority of everyone around this age because hormones are raging and cells are extremely sensitive to testosterone and insulin. Don't get all obsessive and let your acne become a negative symbol of your body-image and self-esteem. If any of your friends are offended by a few small acne spots, do yourself a favor and kick their shallow superficial asses to the curb or show them this report to set them straight, I guarantee that their paradigm on acne and skin health is completely misguided. For 25 years Hoffmann-La Roche has been taking advantage of desperate, vulnerable and naïve teenagers such as yourself who just want to have their acne gone once and for all. Don't take Accutane and play pharmaceutical Russian roulette with your life and long-term health because of measly mild to moderate acne. I know that it's tempting to give in when the almighty acne cure is being dangled in front of your face by the dermatologist, while he or she is simultaneously telling you how great Accutane is based solely on the information they've received from Roche. But it's imperative for you to understand that this s**t alters your DNA/gene expression and reduces stem cell proliferation throughout your whole body (later on I will explain how it does this). Use safe alternative acne treatments instead. There are several out there that work. Take the initiative, do your own research and discover them for yourself. You don't need to take Accutane for your mild to moderate acne, because that would be like using rocket grenades to hunt birds perched on the roof of your house.

Before I launch into my explanation to deconstruct Accutane's mechanism of action, I'm going to provide detailed background information about the history, science, pharmacology and politics of Accutane, vitamin A, and retinoids, including various relevant quotations from experts on this topic as I go along. Accutane is a member of a family of compounds known as retinoids which are related to vitamin A (Retinol). Manufactured by the Swiss pharmaceutical company Hoffmann-La Roche, Accutane, also known as isotretinoin or 13-cis retinoic acid, is a synthetic derivative of vitamin A with a chemical structure that is very similar to vitamin A. It works against the millions of sebaceous glands all over the body, shrinking them and diminishing their output. Because Accutane is one of the biologically active retinoids and is readily converted into all-trans retinoic acid (the metabolic end stage retinoid), Accutane is estimated to be 100 times more potent than dietary vitamin A, which is why the side effects of Accutane closely resemble hypervitaminosis A or vitamin A toxicity. To corroborate, here's another quote by Liam Grant from his statement at the FDA Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee held on September 19th, 2000.

“What is Accutane? Accutane is an analog of vitamin A. It's likened to an overdose of vitamin A. There are many published studies showing that excess vitamin A causes a condition known as hypervitaminosis A. The study I mention here is a 1972 study, and it showed that the ingestion of large amounts of vitamin A is known to cause depression and psychiatric illness. In fact, we have also reports in the 1800’s and the early 1900’s of groups of people with high intake of vitamin A in their diet which caused major depression and psychiatric illness. Therefore, the manufacturers of Accutane, Roche, would have been able to predict with reasonable certainty the main side effects caused by Accutane, including psychiatric side effects and teratogenicity (causes birth defects). And that prediction could have been made with certainty prior to the drug ever being launched here in the United States or in other countries.”

http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3639t2.rtf

In case anyone hasn’t already noticed, the pharmaceutical companies are following directly in the footsteps of the tobacco companies and the story behind Accutane is hands down the most striking example of the unholy alliance between the pharmaceutical industry and their servant the FDA. Nothing else like it has ever happened before, in fiction or in reality and some say the drug has achieved the distinction of being the most dangerous product on the market for the last 25 years. Anybody who says that the introduction of Accutane into the marketplace “was a great step forward in the treatment of acne” is extremely ignorant and has no idea what they are talking about. Since this drug was approved by the FDA in 1982, its warning label has been changed more than 50 times because of adverse reactions. The list of side effects and warnings takes up 7 pages in the newly updated Physician’s Desk Reference. It’s among the top four drugs that attract the most reported adverse drug reactions on the FDA’s database. Due to the incidence of underreporting, the FDA estimates only about 1 to 10 percent of all side effects ever get reported to the agency. Based on this info, one can only imagine how many serious side effects have occurred because of Accutane that have never been reported to anyone. Even Roche has admitted several years ago that there are over 40,000 Accutane adverse drug reaction reports on the database at their headquarters in Basel, Switzerland. As of today 266 cases of suicide have been reported to be caused by Accutane here in the United States, over 5000 psychiatric adverse drug reactions have been reported to the FDA and remember these probably represent only 1 to 10 percent of the actual number that have occurred. Since 1982, hundreds of deaths other than suicide (strokes, heart attacks, Crohn’s disease, and several other causes) have been recorded in the FDA’s adverse event reporting system. In the year 2007 alone, 430 cases of inflammatory bowel disease and 22 deaths were reported in connection with Accutane.

http://www.druglib.com/adverse-reactions_side-effects/accutane/

According to the Ro/Accutane Action Group, www.accutaneaction.com (Roaccutane is Accutane outside the United States) in August of 1997 the FDA issued a warning letter to Roche for failing to submit serious adverse event and death reports in a timely manner. Roche claimed that its computer systems were responsible for delays of up to eight years in complying with the law. Despite all of the shocking adverse drug reaction reports, patients today are still not being adequately warned by dermatologists about more than 150 different side effects this drug can cause and about the possibility that some of these side effects might emerge years or

even decades after someone finishes a course of Accutane when it is too late to change their mind. To put it bluntly, the FDA has never really done anything other than a slap on the hand to punish Hoffmann-La Roche for their blatantly outrageous and murderous criminal behavior. For over two decades they've followed their usual game plan of sticking their heads in the sand when the s**t hits the fan and pretending like it never existed. In her report titled "Babies, Blemishes and FDA: A History of Accutane Regulation in the United States" Julia Green from Harvard Law School writes,

"In September 1983, the advocacy organization Public Citizen petitioned FDA to further adjust the Accutane label. Public Citizen's Health Research Group claimed that the drug's warnings were inadequate and consequently Accutane had been over-prescribed. The group demanded a boxed warning describing the possibility of birth defects, spontaneous abortions, Crohn's disease and several other serious health problems. In addition, Public Citizen asked FDA to require patient package inserts explaining the possible side-effects in non-technical language. FDA declined Public Citizen's requests."

http://leda.law.harvard.edu/leda/data/472/Green.html

A very comprehensive but still incomplete list of Accutane's side effects
http://accutane.poweradvocates.com/accutane_side_effects.html

The greatest kept secret in all of journalism is that journalists are told by their bosses what they can and can't say. Nobody is telling me what I can and can't say in this report, which is why you're able to read my unique perspective on Accutane that you won't find anywhere else. One of the major reasons why the evidence about its side effects has managed to be suppressed for so long is because the mainstream broadcasting networks receive two thirds of their advertising revenue directly from the pharmaceutical industry. And the fox has been guarding the henhouse for a lot longer than people realize. In 1992, under pressure to get drugs passed through the review pipeline quicker, with virtually no debate at all, Congress passed PDUFA (the Prescription Drug User Fee Act) which basically made it so that the pharmaceutical companies now pay the FDA "user fees" to review and approve their drugs, and these "user fees" account for about 50 % of the FDA's budget, a blatant and ridiculous conflict of interest.

FDA drug safety scientists like Dr. David Graham have recommended many times that Accutane be removed from the market, but they are not the ones who call the final shots at the FDA because they are not that high up in the chain of command. "You don't get rewards for doing the work that gets a drug taken off the market" Graham stated before a Senate committee on November 18th, 2004. "I could have given a very mealy-mouthed statement, but then I would have been part of the problem."

"The FDA as currently configured is incapable of protecting America from unsafe drugs."

Forbes.com Face of the Year: David Graham
http://www.forbes.com/2004/12/13/cx_mh_1213faceoftheyear.html

NaturalNews.com The FDA Exposed: An Interview with Dr. David Graham

http://www.naturalnews.com/011401.html

Mercola.com Secrets of the FDA Revealed by Top Insider Doctor
http://articles.mercola.com/sites/articles/archive/2005/08/13/secrets-of-the-fda-revealed-by-top-insider-doctor.aspx

Youtube.com Money Talks: Profits Before Patient Safety
http://www.youtube.com/watch?v=tmp2n-vFdwk

"This 50-minute documentary was created to give an in-depth, academic perspective on the questionable marketing tactics of the pharmaceutical industry, and features the commentary of investigative journalists and medical professionals including Dr. John Abramson, author of Overdosed America, and Prescription Access Litigation Project Director, Alex Sugerman-Brozan. Other notable interviewees include Dr. Bob Goodman of Columbia University, founder of the 'No Free Lunch' program, and Dr. Jerome Hoffmann of UCLA Medical School."

Side Effects: Directed by Kathleen Slattery-Moschkau
http://www.youtube.com/watch?v=oqgtXTRWykc
http://www.youtube.com/watch?v=m-08sIjcyi4

The only Accutane side effects that have ever received any substantial media attention are the birth defects and psychiatric side effects, and even then, the media has completely missed the boat and downplayed their seriousness. But this is likely to change in the near future now that hundreds of new lawsuits are getting into the spotlight.

The pharmaceutical industry is the most powerful and profitable industry in the world, leveraging their influence with the FDA, the FTC, Capitol Hill, lobbyists, and other entities in government to ensure that nothing threatens their monopoly over the treatment of disease in America. Yet again, modern medicine's conventional old-school obsolete attitude is to have acne occur and then treat it after the fact, rather than prevent it in the first place. As is the case with many other health conditions, several alternative natural remedies and dietary modification programs exist that are highly effective against acne, but the problem is nobody knows about them to take advantage of their availability because they are not being promoted to the masses, because they are not a patentable, profitable, pharmaceutical drug like Accutane. The current FDA regulating system states that it is illegal to make medical claims about a remedy being effective for a disease unless it has been evaluated and approved as a drug by the FDA. You read that right. The FDA has set as law that only a drug can cure, prevent or treat a disease, absolutely nothing else can. For example, if you say that an orange cures the disease of scurvy, technically you've broken the law and could be thrown in prison. There is no incentive to spend the huge amount of money needed to get a natural remedy approved because natural remedies cannot be patented. So, according to this logic and these rules, technically it would be illegal for a dermatologist to recommend diet modification or a safe alternative natural remedy for their patient's acne instead of the toxic chemotherapy drug Accutane or antibiotics, which is incredibly insane. Therefore a lot of people mistakenly believed that Accutane was their only available option because the dermatologist had erroneously told them that nothing else worked. Also, why would dermatologists recommend a safe natural remedy when Roche has been giving

them many incentives to prescribe Accutane "off-label" to many patients with mild to moderate acne. On a side note, doctor's often claim they don't have time to read the latest Physician's Desk Reference sections on the drugs they prescribe, which would keep them up-to-date on all the side effects. This is preposterous. I'm not a doctor (last time I checked) and it only took me 25 minutes to read the entire 7 page section on Accutane in the PDR.

The future of medicine does not involve foolishly bombarding the body with toxic drugs like Accutane. The real progress that is being made in health care comes from physicians who are thinking outside the box and providing a type of care that takes the entire person into account, searches for the root underlying cause, devises specific individualized treatment plans, and often doesn't require drug therapy of any kind. Proper nutrition, clean air/water, and stress reduction techniques always go a long way in helping people become healthier. Yes there are definitely important truly "safe and effective" drugs out there, but they are few and far between and probably not more than 200 of them are actually needed. Improvements toward this new vision of health care have been occurring gradually over last few years, more and more physicians are beginning to gravitate away from the conventional paradigms by becoming more progressive and open-minded, but before significant change can take place, modern medicine needs to start viewing the human body as a dynamic entity instead of a collection of isolated parts.

Great article by Dr. Joseph Mercola that includes a petition to sign to help reform the FDA
http://articles.mercola.com/sites/articles/archive/2009/02/02/here-s-your-chance-to-change-the-fda-i-need-your-help-on-this-one.aspx

Simple Ways to Stop Acne Naturally
http://articles.mercola.com//sites/articles/archive/2009/03/28/Simple-Ways-to-Stop-Acne-Naturally.aspx

Natural Acne Solutions
http://www.natural-acne-solution.com/accutane-side-effects.html

Vitamins are essential compounds for life to occur and to maintain healthy function of all of the metabolic reactions in a living organism, which is why they are called vitamins. The word vitamin originated from the term "vitamine" which was coined in 1911 by the Polish scientist Cashmir Funk to define a group of compounds that are considered vital for life. Vitamin A (Retinol) plays a vital role in vision, skin health, gene expression, reproduction, fetal development, growth, bone metabolism, immune response, and the cellular formation of tissue. In the complete absence of vitamin A for an extended period of time, people go blind, hence it is extremely important to consume some vitamin A on an ongoing basis. Normal RDA (recommended daily allowance) doses of natural vitamin A in the vicinity of 5000 IU are completely harmless and greatly beneficial to our health. But like many other things in the body and in the field of endocrinology, maintaining the correct balance is the key, and severe consequences can result when this balance is thrown off. This is especially true with vitamin A and the retinoids. When vitamin A is consumed in the diet, it is then converted by the body into biologically active retinoids that influence the expression of genes, also known as protein transcription, the biological process of building structures that are the essence of life and that sustain life. Humans and mammals cannot utilize any dietary protein without the presence of

vitamin A, therefore retinoids are vitally important in the mechanism of protein transcription. In fact, retinoic acid is considered to be the great "impresario" orchestrator of life. Being the chief regulator of protein transcription and cell division, it is arguably the body's most important master molecule. Beta-carotene (non-toxic precursor pro-vitamin A), a healthy beneficial antioxidant found in several fruits and vegetables, is converted into vitamin A in the liver on an as needed basis in a tightly regulated process, which illustrates one of the safety mechanisms set up within the body to prevent vitamin A toxicity, because vitamin A performs the crucial function of regulating the gene expression and protein transcription. Accutane is downstream at end of the retinoic acid metabolic pathway so it bypasses these biological safety check points.

The problem with Accutane is that it gives all the other vitamins a bad rap. As a general rule, vitamins and nutritional supplements are all very safe health enhancing compounds, but there are a few exceptions and vitamin A is one of them, because it has by far the worst toxicity profile out of all the vitamins. A high degree of individual variability exists with vitamin A toxicity. Some very sensitive individuals experience signs of toxicity at only 50,000 IU per day, but most people don't experience toxicity until doses above 300,000 IU per day are achieved, which is roughly equivalent to taking one dose of Accutane. Even a low dosage of Accutane (10 mg to 20 mg) is still a hefty amount of vitamin A. To avoid birth defects, pregnant women should never consume more than 10,000 IU of vitamin A per day in their diet or supplements. It's ok to incorporate natural vitamin A into an acne treatment program, just make sure to stay below a daily dose of 30,000 IU. If for any reason you do decide to exceed this threshold and something weird happens to your body, don't come back and say that I didn't sufficiently warn you. Vitamin A toxicity resulting from dietary factors like excessive consumption of animal liver or excessive intake of nutritional supplemental vitamin A is very rare because all supplement manufacturers set their dosages at or near the 5,000-10,000 IU upper limit. Therefore someone would seriously have to go out of their way to intentionally poison themselves with supplemental vitamin A. But the horrible toxicity of vitamin A has been experienced by millions acne patients around the world as a result of dermatologists irresponsibly and carelessly handing out Accutane prescriptions "off-label" to many many people with mild to moderate acne, not severe cystic acne, which is the only medical condition Accutane is approved to treat. Roche has exploited the one vitamin with the worst toxicity profile, creating a potent, dangerous drug out of it. Accutane induces a severe form of vitamin A toxicity, which is how it reduces acne, reduces cell division and severely dries out the entire body by effectively slamming shut all of the sebaceous (oil) glands in the skin and degrading the glycosaminoglycan water-holding protein molecules collagen, hyaluronic acid, elastin, and chondroitin sulfate in connective tissue everywhere, leaving the person in a chronically dehydrated hung-over state because the terrain throughout their whole body has been literally turned into a desert, they are unable to retain moisture between their cells. Severe systemic dryness is the hallmark sign of vitamin A toxicity. The more toxic dose of Accutane or vitamin A consumed, the more severely dried out the entire body becomes, especially the skin, eyes, and mucous membranes. The chronic life-long latent effect of extreme dryness doesn't happen to everybody, but it does happen (with varying degrees) to everybody while they are taking Accutane. Depending on the severity of Accutane's original assault on the person's DNA protein transcription mechanisms, some people recover from their side effects with time, others aren't so lucky. And from what I can tell, there's no way of knowing in advance which group somebody will fall into. If you've taken Accutane in the past (a lot of people have) and your body currently feels normal, healthy, and without any severe

dryness, consider yourself extremely lucky and don't ever take this drug again. Vitamin A toxicity is very real, and more common and deadly than people realize, all because of Accutane.

Here's an extremely important question for all the current prospective Accutane users to ponder over. Do you think it is better to have extra oily supple skin or chronic life-long dry skin, the latter being a potential outcome of using Accutane. Don't know? I'll help you out with another hint. Take a look around, how many people do you see in their 50's to 70's with oily skin or acne? Having acne prone oily supple skin is a sign of youth because as the body ages the skin gradually and inevitably dries out. If somebody were to design the perfect drug to accelerate the aging process by prematurely drying out the entire body, that drug would be Accutane. Roche doesn't disclose this fact in their product information on Accutane because their primary motive is profits not patient safety and they know that teenagers don't ever think this far ahead when the prospect of clear skin is on the line. This drug permanently shrinks the oil glands everywhere and damages the ability to regenerate water-holding molecules, like the glycosaminoglycan hyaluronan AKA hyaluronic acid, which holds water hundreds of times its own weight in the skin and other areas of connective tissue. These specialized molecules in connective tissue are extremely important because they are the scaffolding that holds the body together, they facilitate cellular waste removal, and they are the Internet of the body, performing the crucial role of facilitating cell-to-cell communication. Imagine the body as a giant brick building with the cells being the bricks and hyaluronan being the network of white mortar connecting them. People erroneously believe that if Accutane dehydrates and dries them out too much, they can just drink more water. But it doesn't exactly work that way, because Accutane damages the ability to regenerate the water-holding molecules that enable tissues to retain the water and fluids that the person is drinking (in some cases, drinking lots of water can help alleviate the severe dryness but it's not a complete solution to the problem). Just like many other cells that are rapidly dividing and constantly turning themselves over, the hyaluronan water-holding matrix also turns itself over often. An interesting fact about hyaluronic acid is that the average 70-kg man has roughly 15 grams of it in his entire body, and about one-third of this is turned over (degraded and synthesized) every day. The body has other natural biological strategies for retaining water. Dr. Susan Lark, a respected and renowned anti-aging doctor states, "remember when you were younger and your skin just glowed naturally? Well the reason for that glow was the natural oil in your skin. Scientists call it *sebum*. And it helps prevent "trans-epidermal water loss" – which is a fancy term for losing all the moisture in your skin." It's no wonder that a common testimonial given by young people taking Accutane is that they feel like an 80 year old person in a 23 year old body. Dermatologists are supposed to be in favor of anti-aging, but for the past 25 years, they've been passing out a drug that acts to accelerate the aging process by severely drying out the entire body. Aging is a side effect of being alive, but in the case of Accutane, it's appearing more and more likely that aging is the predominant side effect.

The FDA refuses to acknowledge aging as a disease, and for them, everything that is not acknowledged is prohibited, this includes any company that attempts to promote the evidence in scientific literature of the life extending properties of vitamins and other nutrients. Several high quality nutritional wellness products exist on the market today that do indeed have research validated life extending properties. But vitamin A is the major exception to the life extending properties of wellness nutrition, because even though some vitamin A is essential for health and longevity, too much vitamin A is dangerous and will actually elicit the opposite effect by causing

tissue function changes that mimic accelerated aging. Nutritional supplement makers always list their vitamin A dosage recommendations in the safe range because they value people's safety. Roche on the other hand has no problem with promoting their potent dangerous pharmaceutical vitamin A derivative (Accutane) to large numbers of acne patients, while not telling them what it is or how it works. Meanwhile the FDA sits back and does nothing. Even though the evidence is overwhelming that taking Accutane accelerates the aging process (by reducing stem cell proliferation and causing severe dryness), the FDA doesn't care, because in their view, aging is not classified as a disease.

People have absolutely no idea what they are getting themselves into when they take Accutane. They take it and hope for the best. Patients starting out on this drug never imagine they might end up with over a dozen side effects after they finish taking it. Chronic dry eye, dry skin, dry nasal passage, eczema, diffuse hair loss, peeling skin, erectile dysfunction, cheilitis, diabetes, sjogren's syndrome, ibs, joint pain, muscle weakness, mental changes, insomnia, dizziness, fatigue, etc, all together is pretty much impossible for somebody in their early 20's to experience, unless they've been exposed to Accutane that is. Of course most of the doctors these patients visit deny that all their problems could be from Accutane. This is the same repeating story I've encountered over and over, but in some ways you have to cut these doctors some slack. This situation has never happened before with any medication and no one seems to get it. People often don't associate problems with Accutane because of the latency of them. Some have their worst side effects start months after their course, many five years after and others even up to 10 - 15 years after. Some last longer before the side effects kick in and to some it happens right away while they're on the drug.

Standard operating procedure at Hoffmann-La Roche has always been to blame the patients for their psychiatric side effects, despite the fact that vitamin A toxicity has been linked to mental illness for hundreds of years ever since the European explorer Gerrit de Veer and the Arctic explorer Elisha Kane and his crew experienced psychotic reactions and other severe health problems after they consumed polar bear liver, which was later found out to contain lethal concentrations of vitamin A. In the past and even up to the present, many nutritional health experts and doctors have not reported or publicized the information about the potentially severe side effects of vitamin A toxicity as much as they should. As a result people think that all vitamins are safe and non-toxic in high dosages, and when they go to the dermatologist and the derm tells them that taking Accutane is like taking high amounts of vitamin A, they automatically think to themselves, "oh it's just a vitamin, it's harmless." These people are definitely in for a big surprise. Anybody who wants to observe the nasty and horrible effects that occur with severe vitamin A toxicity needs to look no further than the side effect profile of Accutane. Pharmacologist Dr. James O'Donnell gave a remarkably informative presentation outlining the similar toxicology of Accutane and vitamin A during the first Accutane Congressional Hearing held on December 15th, 2000. Here are the most significant highlights.

"I am an Assistant Professor of Pharmacology at the Rush Medical College in Chicago, and I am also a licensed pharmacist. I do not hold any federal grants, although I have testified as an expert witness in matters against Roche. I would like to project my one slide, and leave it projected for the course of my comments. My review has included the basic pharmacology and toxicology of vitamin A, and if we can focus just on the top three chemical formulas there, from the audience

you won't be able to see that, but please take my word that the three molecules of retinol (vitamin A), tretinoin (Retin-A), and isotretinoin (Accutane), are practically identical. As a chemist and a pharmacologist, looking at these three chemicals, not knowing anything different, you would predict the same actions, including the same toxicities."

"Vitamin A is an essential factor in physiological growth, visual function, epithelial cell differentiation and reproduction and is believed to exert its influences at the DNA level where it plays an important role in regulating transcription of a number of genes."

"An intake of retinoids greatly in excess of requirement results in a toxic syndrome know as hypervitaminosis A. Some or all of the symptoms of hypervitaminosis A also are the major toxic effects that are manifest during the therapeutic use of natural and synthetic retinoids in the treatment of skin disorders. Accutane, being an analog of vitamin A, shares many of the side effects experienced with vitamin A."

"Accutane is associated with a long list of side-effects which are frequent, varied and at times severe. The most commonly occurring adverse reactions are those involving the skin and mucous membranes, which occur in all patients treated with Accutane. Other side effects reported include skin fragility, pyogenic granuloma-like lesions, epidermal blistering, gastrointestinal intolerance and alopecia."

"Blepharitis and conjunctivitis associated with Accutane use were recognized well before its marketing. Corneal opacities and acute myopia have been reported in government publications and in the ophthalmologic literature. Other ocular reactions include optic neuritis, cataracts, decreased night vision, blurred vision and photosensitivity. Pseudotumor cerebri (PTC) and headaches are also associated with the drug."

"There are two types of hypervitaminosis A, acute and chronic. Acute hypervitaminosis A results from ingestion of a very high dose of vitamin A over a short period of time. Signs and symptoms include drowsiness, irritability, irresistible desire to sleep, severe headache due to increased intracranial pressure, dizziness, blurred vision, vomiting, papilledema, and, after 24 hours, widespread peeling of the skin. Chronic hypervitaminosis A is more common than the acute form and results from continued ingestion of high doses of vitamin A for months or even years. Symptoms include anorexia, dry itchy skin, dry eyes, alopecia, increased intracranial pressure, fatigue, irritability, somnolence, skin desquamation, fissuring of the lips, pain in the legs and forearms, hepatomegaly, neurologic disturbances and lethargy. Elevated blood lipids are also common. This reads just like the Accutane package insert."

"I referred to earlier, describe patients who are psychotic, who have schizophrenic like symptoms, and suicides have been associated with vitamin A toxicity. The condition of vitamin A toxicity causes a change in the brain chemistry. The condition that brings vitamin A toxic patients to the hospital is a swelling of the brain."

"We have a long history of psychiatric toxicity associated with Vitamin A. It's not surprising that we have similar reports of similar psychiatric toxicity associated with Accutane."

"An FDA memo of February 1998 stated that for a majority of the evaluable cases of suicide, suicide attempt or suicide ideation associated with Accutane, for the majority, there was no antecedent history of depression, and the patients were not noted or known to be depressed in the time period prior to their suicide. As a result of underreporting, the actual number of suicides could be 10 times greater than the number of reports."

"The numbers are alarming. The price is death and destruction of our children and young adults."

"We don't need absolute scientific proof in order to recognize a signal and act on it."

"Indeed, the mechanism of action of Accutane in treating acne is unknown! In fact, the FDA rarely has more than signal before significant warning changes and sometimes drug withdrawal occurs."

"In my opinion, we have sufficient evidence to be very concerned and take some corrective steps. The link between vitamin A toxicity, including central nervous system toxicity, and Accutane is indisputable."

http://www.accutaneaction.com/Hearings/transcripts.htm

Investigative health journalist Bill Sardi published a compelling and insightful report on Accutane and its long-term side effects titled *Accutane: a modern horror story*. This report came out five years ago, so some of the statistics might be outdated, but it is very thorough and well referenced. One important topic he covers is how oral hyaluronic acid supplementation might improve the extreme dryness of tissues caused by Accutane. Former Accutane users suffering the chronic latent effects of severe systemic dryness of their skin, eyes, lips, mouth, and nasal passage should consider taking oral hyaluronic acid supplements. Hyaluronic acid is the scaffolding that holds the human body together. It cushions joints and nerves, dilutes toxins and serves as a barrier against the spread of disease.

http://www.naturalhealthlibrarian.com/

"The medical community and a drug company are in a state of denial regarding side effects caused by Accutane. Nutritional supplements should be taken during Accutane therapy to ward off potential side effects. Dietary supplements may also remedy chronic side effects experienced by former Accutane users. Urgency is required to search for safer alternatives than Accutane for the treatment of acne."

"Mathew Hamilton's story is a case in point. At the age of 15, and with a mild case of acne at best, his dermatologist in Cape Town, South Africa, prescribed Accutane (Roaccutane outside the USA). Matthew only experienced the common symptoms of dry skin and chapped lips while taking the medication. Otherwise, things were uneventful. Then four months after finishing treatment, Matthew had a suicidal episode, a latent side effect of the drug produced by shutting off the production of serotonin, a mood-controlling brain chemical."

"A year later, Matthew was still struggling with suicidal attacks for no apparent reason. Around this time his hair began to fall out and his scalp became itchy. Backaches and clicking sounds in all of his joints appeared. Instead of graduating as the top student in his high school, as anticipated by his previous school record, Matthew was struggling with the side effects of Accutane. Muscle weakness ensued. Then hair loss spread to his eyebrows, eyelashes, and other body hair. His eyes were always dry and floaters, what appear as cobwebs or black globs in the visual field appeared. Nightmares and bouts of depression were common."

"Matthew began his own investigation. While literature provided by Roche, the manufacturer of Accutane, states that side effects magically go away after ceasing use of the drug, he began to make contact with people who had taken the drug when it first became available in 1982 and were still suffering with side effects 21 years later."

"Then Matthew found another important link to his other side effects. Accutane, also switches off the production of hyaluronic acid, the water-holding molecule in the connective tissue between living cells in the body. Hyaluronic acid is concentrated in the joints, skin, scalp, and eyes, exactly where all of Matthew's symptoms were concentrated. Scientific studies appear to confirm Hamilton's suspicions regarding hyaluronic acid. The destruction of hyaluronic acid would explain the universal symptoms of dryness associated with Accutane use, the dry eyes, hair, skin, and joints."

"Just as Accutane causes the drying up of secretions from the sebaceous glands, it also inhibits the secretion from other glands as well. Accutane is not specific to the oil glands in the skin. It dries out the whole body."

"One of the common statements heard from young Accutane victims is: *I feel like a 23 year old grandmother or grandfather.* It's not surprising that these people feel old before their time. Progeria is known as a disease of premature aging. Progeria children develop premature wrinkled skin, hair loss, cataracts, and other signs of advanced aging. Progeria is universally diagnosed by an elevated losss of hyaluronic acid in the urine. Progeria children excrete up to 17 times more hyaluronic acid than healthy children. Were these Accutane side effect sufferers simply mimicking symptoms similar to progeria?"

"Oral hyaluronic acid (HA) supplements are relatively new. They offer hope for restoration of tissues adversely affected by Accutane. Just 1000 milligrams can hold or gel 6 liters of water in the body. Oral hyaluronic acid supplements have been reported to lessen or eradicate joint pain in cases of osteoarthritis, eliminate back pain caused by swollen vertebral discs, refill skin tissues to the point of reduction of wrinkles, cause floaters in the eyes to disappear, and improve thickness and luster of hair. The production of hyaluronic acid may be impaired in Accutane users. Supplementation may be beneficial."

"Accutane kills by the hand of its users. They swallow the Accutane pills and they commit suicide. It's a perfect cop out for the pharmaceutical companies. The drug company's fingerprints are all over the lethal weapon, but they escape responsibility by having Accutane users sign a consent form."

“There are a number of reports of side effects associated with Accutane that are not generally listed or highlighted by the manufacturer.”

“A seeming paradox exists with Accutane. Why does it induce night blindness when vitamin A is required for rhodopsin, the night vision chemical? For decades it has been known that a shortage of vitamin A produces night blindness. By 1986 the first cases of poor night vision were being documented among Accutane users. [Archives Ophthal 104:831-37,1986] Night blindness has been reported to occur within two weeks of starting Accutane (20 mg daily dose). [Australia J Derm 40:208-10, 1999] The occurrence of night blindness with Accutane suggests this drug in some way interferes with vitamin A metabolism. A similar paradox exists for Accutane and dry eyes. Vitamin A is a treatment for dry eyes. Vitamin A is required for the production of mucin by the goblet cells.”

“One thing is clearly established. The side effects of Accutane don’t wear off for everyone. For example, an 18-year Accutane sufferer (1985-2003) started with low back pain and fatigue about 6 months following Accutane treatment. Then later inflammatory bowel disease occurred. Arthritis in other joints and mental depression became part of the syndrome. In 1992 Sidney Lerman reported that Accutane therapy produced irreversible cases of dry eye two years following cessation of therapy and also some cases of cataracts in relatively young patients (teens to 40’s), which demonstrates that some of the ocular side effects caused by this drug ‘are not reversible when the drug is stopped.’ [Lens Eye Toxicology Res 9: 429-38, 1992]”

“Acne patients need to seek safer alternative treatments. Dermatologists are not likely to aid patients in the quest for alternative therapies. With some guidance, many acne patients are likely to find safer remedies outside the dermatologist’s office. Doctors will argue there isn’t sufficient evidence to prove that alternative therapies are more effective than Accutane. However, the evidence for alternatives is lacking by the very reluctance of the medical community to explore their use.”

To understand how Accutane causes dry, irritated eyes, do this experiment. Fill two small bowls with water and place them side by side. Next, pour any type of oil into one bowl but not the other. Now wait a really long time and then observe what happened to the bowl without any oil. There is less water in this bowl due to evaporation, but none of the water in the other bowl has evaporated because the oil formed a barrier layer on the surface. This analogy illustrates what happens when Accutane causes the meibomian gland (a specialized sebaceous gland) in the eyelids to secrete less oil. The specific function of the meibomain gland in the eyelids is to secrete a protective oil layer into the tear film, which prevents tears and the eyeball surface mucosal layer from evaporating. The problem with Accutane is that it does not know the difference between the sebaceous glands all over the skin and the sebaceous (meibomian) glands inside the eyelids. Therefore when Accutane partially or completely destroys the meibomian glands, decreasing oil and lubrication, tears evaporate much quicker, the mucosal layer becomes degraded, and potentially permanent, severe, irritating dry eye syndrome is the result, causing eyes to drag around in their sockets.

This is why people are NOT supposed to use eye drops while they are taking Accutane (dermatologists don't usually tell their patients this), because if their eyes are getting dry to the

point that they constantly need to use eye drops, it means that they must reduce their Accutane dosage immediately, unless they want Accutane to give them a permanent case of dry eye syndrome where they'll have to use eye drops, won't be able to wear contact lenses, and have constant eye irritation/pain for the rest of their life, and be much more susceptible to conjunctivitis, eye infections and cataracts as they get older.

Pseudotumor Cerebri otherwise known as intracranial hypertension or swelling of the brain is one of several serious side effects of both vitamin A toxicity and Accutane. The drug brochure provided by Roche way back in the 1970's states that adverse reactions to Accutane "are essentially those of hypervitaminosis A." At an FDA meeting in 1983, Dr. Del Vecchio described Accutane's side effects and said that "just about everything that happens with Accutane may happen with vitamin A overdosage."

http://www.accutaneaction.com/Studies/index.html

Most of the Accutane side effects resemble acute or chronic hypervitaminosis A, but paradoxically, a few of Accutane's side effects like permanent night blindness, resemble vitamin A deficiency or hypovitaminosis A.

Evidence about Accutane's propensity to cause psychiatric problems had been building up all throughout the 80's and 90's, but nobody, not even the dermatologists were talking about it or acknowledging that it was happening. Despite all of the accumulating evidence, dermatologists announced to everyone that there was absolutely no link between Accutane and psychiatric side effects. A shocking report appeared in The Journal of the American Academy of Dermatology back in 1987 that was titled "Hypervitaminosis A syndrome: a paradigm of retinoid side effects." (J Am Acad Dermatol 1987;16: 1027-39) I guess none of the dermatologists bothered to read their own journal because this report should have raised some serious red flags about the connection between retinoids and psychiatric toxicity. In this report it says that physicians utilizing retinoids should be aware that in the past few decades patients have been committed to psychiatric hospitals for severe depression and schizophrenia when mental changes were due to hypervitaminosis A. The report also says that investigative trials of new retinoids have shown how important it is to become familiar with hypervitaminosis A syndrome because so many side effects associated with new retinoids (such as Accutane) have previously been encountered in patients with chronic hypervitaminosis A.

Hoffmann-La Roche has always continued to deny that Accutane can cause psychiatric side effects like depression and suicide, but they do not acknowledge the fact that vitamin A toxicity has been consistently linked to mental illness for centuries. In 1597, European explorer Gerrit de Veer spent the winter in Nova Zembla. His diary of the experience revealed how he and the rest of his men became "gravely ill and feared for their lives" after eating polar-bear liver.
250 years later, in 1856, the Arctic explorer Elisha Kane and his crew experienced extreme fatigue, drowsiness, irritability, headache, bone pain, peeling skin, vertigo, and psychosis after they consumed polar-bear liver, which was later determined to be poisonous because it contains lethal amounts of vitamin A. A one-half pound serving of polar bear liver will deliver about 9,000,000 IU of vitamin A to your diet, an extremely lethal dose that will make all your skin peel off before you die. Fatal cases typically end with full-body skin loss, liver damage, delirium,

hemorrhage, and coma. This danger of toxicity resulting from the ingestion of bear liver has long been known by indigenous Inuit people of the Arctic regions, but many Western explorers and hunters had no knowledge and ended up learning the hard way. A common practice among the Inuit is to bury polar bear livers deep under the ice or toss them into the sea in order to prevent their sled dogs from chowing down their last meal. Polar-bear liver contains about 1 million IU of vitamin A per ounce (the RDA for adult humans is only 5000 IU), which is why if you decide to snack on it, the top layer of skin on your hands and other places all over your body will come off in giant sheets. Not surprisingly, peeling of the skin on the palms and soles and skin coming off on various places of the body is also a potential side effect of Accutane. An article titled "The Vitamin A Content and Toxicity of Bear and Seal Liver" dated 1943 described what happened to these explorers after they ingested polar bear liver. The side effects of eating polar bear liver are very similar to the side effects of Accutane.

The Vitamin A Content and Toxicity of Bear and Seal Liver
http://www.biochemj.org/bj/037/0166/0370166.pdf

The abstract of Dr. James O'Donnell's article titled "Polar Hysteria: An Expression of Hypervitaminosis A" states,

"Isotretinoin (Accutane) is a drug closely related to the chemical structure of Vitamin A. The pharmacology and toxicology of these two retinoids is similar enough to warrant comparison. Accutane is a powerful drug which its manufacturer, Roche, indicates is limited for severe recalcitrant nodular acne. This potency is also reflected in Accutane's well-known ability to produce severe birth defects if taken during pregnancy. Less well-known is the risk of this lipid soluble chemical to affect the Central Nervous System. Reports of intracranial hypertension, depression, and suicidal ideation with Accutane use have prompted an examination of this serious and life threatening potential. Though Roche has added a warning to its product label for signs of depression and suicidal ideation, this product is being overprescribed for all forms of acne, including mild cases and moderate acne that have not been treated with alternative medications, which have a lesser risk of depression and suicide. There is no contesting that this drug is effective at clearing up the most severe forms of acne, but the public must be informed of its proper, limited indication for use; depression and suicide can follow in patients with no prior history of psychiatric symptoms or suicide attempts."

Polar Hysteria: An Expression of Hypervitaminosis A
http://www.americantherapeutics.com/pt/re/ajt/abstract.00045391-200411000-00015.htm;jsessionid=JJ7HJGPKtBtS90xJTWXtLfvtd8QRWpTYzr2Hl8vJpgXZkcnwQN1Q!-450575803!181195629!8091!-1

Hypervitaminosis A and Fractures
http://content.nejm.org/cgi/content/short/348/4/347

Most animal liver is safe to eat (for people who have never taken Accutane), but it should be noted that bear, seal, and husky livers are not safe for anybody. In 1913, the Swiss explorer and skiing champion Xavier Mertz embarked on an Antarctic expedition with the Australian Sir Douglas Mawson and Lieutenant Edward Ninnis. While attempting to cross the Ninnis Glacier,

Ninnis fell into a crevasse, along with six dogs, the tent and most of the supplies. With only a few days worth of rations left and 315 miles from the main base, Mertz and Mawson now faced the impossible challenge of getting back to safety without sufficient food. They began to eat the livers of their husky sled dogs and over a few weeks' duration both were poisoned, experiencing dryness of the nose, mouth, eyes, cracked lips, hair loss, irritability, fatigue, and loss of all skin on their legs, hands, feet, genitals, "skin coming off whole body" according to Mawson's diary. Even the thick skin on the soles of their feet came off, leaving areas of the underlying tissue bloody and exposed. Mertz consumed more liver and eventually became fatally poisoned after developing severe stomach pains, diarrhea, and going insane. The dreadful details of Mertz and Mawson's ordeal can be read in the British Medical Journal articles "Man's best friend?" and "Vitamin A and Sir Douglas Mawson." Several parallels to the side effects of Accutane are exceedingly apparent.

Man's best friend?
http://archive.student.bmj.com/issues/02/05/life/158.php

Vitamin A and Sir Douglas Mawson
http://www.pubmedcentral.nih.gov/pagerender.fcgi?artid=1602734&pageindex=1#page

Acne drug has serious side effects
http://www.cbc.ca/marketplace/pre-2007/files/health/accutane/index.html

Here's a quote from the above article describing the controversy over the psychiatric side effects,

"Hoffmann-La Roche says there is no causal relationship between Accutane and depression or suicide. Experts point out that no one factor causes suicide and that a high percentage of Accutane users -teens and young adults- are already more likely to get depressed. But some doctors say there's plenty of evidence to support a link between Accutane and depression and suicide. And they argue that evidence of the link dates back to Arctic explorers of the 19th century. Diaries tell of how some sailors suffered polar madness. Experts today say it was from eating polar bear liver, which is full of vitamin A. In large doses Vitamin A can cause brain toxicity, seizures, and behavioral changes. Accutane is a derivative of vitamin A."

The following transcript from the first Accutane Congressional Hearing held on December 15th, 2000 illustrates the wide-spread lack of knowledge about the severe consequences of vitamin A toxicity, even among dermatologists. Chairman Burton expressed his own concern and urgency by taking the initiative himself to inform all the dermatologists in the nation about Accutane's psychiatric side effects, because as expected, the people from Roche and the American Academy of Dermatology were reluctant to do it.

CHAIRMAN BURTON: Then why don't you just go ahead and send a fax out to all the dermatologists in the country, saying this is a risk, and many dermatologists evidently don't know about it. There was testimony before the Congress of the United States by people who have lost children, who knew nothing about it, even though it had been publicized on the Internet, and so we want to make sure you know about it. Why don't you do that?
DR. PARISER: I'll check into it.

CHAIRMAN BURTON: Would you do that?
DR. PARISER: All right.
CHAIRMAN BURTON: And if you don't, do me a favor. Give me a list of all your members, and I'll send the dammed thing out. Because I don't want to have other people coming before our Committee with their kids being dead because possibly Accutane caused it. Now, let me ask you a question, Dr. O'Donnell. You said that the people who ate polar bear livers in the middle 1880's that were on polar expeditions.
DR. O'DONNELL: That's right.
CHAIRMAN BURTON: And they had psychotic events because of the large amounts of Vitamin A they were consuming in the livers of polar bears; is that correct?
DR. O'DONNELL: Yes, sir.
CHAIRMAN BURTON: And was this just an isolated incident, or was this something that happened more than once?
DR. O'DONNELL: There were several reports. Not many were published, but it was common knowledge that people had to avoid excessive use. Similar reports since then have published neurotoxicity, toxic psychosis, but the first report that I referred to was a polar expedition in 1856.
CHAIRMAN BURTON: So Vitamin A in large quantities definitely causes the kinds of problems you're talking about, and that is what Accutane, in main part, is made up of?
DR. O'DONNELL: Yes, sir.
CHAIRMAN BURTON: One of the things that bothers me, the question that was just asked by Mr. Waxman, you kind of just, we aren't really geared up to get that kind of information out to the American people. That's kind of a cop out, I think, isn't it? I mean, the Food & Drug Administration is supposed to be the person or the group that guarantees the safety and the efficacy of pharmaceuticals and drugs for the people of this country, and if something is going awry, you're saying, oh, it takes so much time to get the information out, and I mean, 19,000 dermatologists, you could send letters out tomorrow to all of them, in big bold print, to all the pharmacists in the country, and you don't send, put it on the email. You know, there's all kinds of ways to communicate in this age, and I think it's a real cop out for the FDA to say, oh, we can't do that. The other thing I want to ask you is this: In 1850 something, polar bear livers were causing psychiatric problems on people that were eating them, because of large amounts of Vitamin A. This pharmaceutical expert, or pharmacologist
MR. O'DONNELL: Both.
CHAIRMAN BURTON: Both. Indicated that the brain swells up when you have too much Vitamin A in it, which causes severe problems. When the testing was done, back in the 1980's, before Accutane was put on the market, did anybody check mice brains? Did they give them large amounts, or any kind of animals large amounts of Vitamin A, to check to see if it caused any side effects? Did anybody check that out?
DR. HUENE: I would add that the label does address a condition known as psuedotumor cerebri, which is I think the brain swelling that you referenced, that was known to be related to hypervitaminosis A.
CHAIRMAN BURTON: When we hear of people whose children who have committed suicide, or who have had adverse events occur because of Accutane, and they didn't even know anything about this, were never warned by their dermatologist, were never warned by their pharmacist. They had no knowledge. They went home, started giving their child the pills, and those side effects occurred. My gosh, what a mistake. What a tragedy. In any event, we would like to have

that information submitted for the record, and I would like to have a list, if you don't have it, of all the dermatologists in the country, and if your association won't contact them, then I'll figure out a way to do it myself, and the Committee will. And I think that we ought to put on our email to all pharmacists in the country the warning that Roche is now putting on their label so that they will all be aware of it as well.

Also at this Congressional Hearing, many individuals and their families testified about their experiences with Accutane.

"As Amanda's depression worsened despite the therapy and medication, the only thing we could visibly see working was the Accutane. Her lips dried out, cracked and bled; her joints ached, and she was always thirsty. But the dermatologist told us that that was just the effect of Accutane, nothing to be worried about, just don't get pregnant."

"Stacy and Mike Baumann of Mundelein Illinois lost their son Daniel to suicide in December 1999. Daniel began Accutane treatment in July 1999. He suffered many adverse effects; chapped lips, dry skin and itching, joint and muscle pain, headaches, nausea, loss of appetite, mood swings, and insomnia. The physician thought his depression was school-related and never mentioned the FDA warning."

"I met a friend from high school not long ago and it turns out she was on her way to pick up a prescription for her son of Accutane. When I asked if she was aware of the potential risk, she looked at me like I was crazy. I asked her if she was counseled by her dermatologist, who was different from ours, and she said she was not. I asked her if this drug was prescribed when other remedies had failed, and found that it had been prescribed first, before any other remedies had been tried."

"Our children are dying because a drug company makes lots of money from this drug. This is the same company, cited for once advertising that Accutane helped depression, this just one month after the FDA required the warning about suicide. We would never allow our children to play Russian roulette with a gun, but we allow that to happen every time a prescription for Accutane is given."

http://www.accutaneaction.com/Hearings/transcripts.htm

Michigan Congressman Bart Stupak has been working relentlessly to create more awareness about the dangers of Accutane and its psychiatric side effects ever since his family tragedy back on May 14th, 2000, when his son Bart Jr. fatally shot himself near the end of his course of Accutane. During the second Accutane Congressional Hearing held on December 15th, 2000, Stupak blasted the FDA, Hoffmann-La Roche and dermatologists for failing to protect young people from the side effects of Accutane.

"We cannot allow the drug manufacturer and the FDA to continue to turn a blind eye to the lives lost, families devastated and dreams dashed by an acne drug. The American people, our children, are not collateral damage in the scheme of corporate profits!"

"The drug manufacturer, Hoffmann-La Roche, Roche here in the United States, has continued to put profits before people. They have done everything possible to prevent the American people from learning of the psychiatric injuries and deaths associated with Accutane. Even, today, I'm sure Roche will deny any casual effect of Accutane with the abortions, deaths, and suicides caused by their product."

"Accutane is a powerful, dangerous drug with devastating consequences for some patients. The birth defects caused by Accutane are horrific. The FDA's response to the birth defects and psychiatric events has been inadequate, irresponsible and unacceptable. Thousands of babies, teenagers, and young adults have died prematurely. While the FDA has been aware of the birth defects since at least 1982 and the psychiatric injuries since 1985, their responsibility to protect the public has been inconsistent and without direction."

"The Accutane birth defects are similar to Thalidomide, which is a tightly controlled drug in this country and is used by a group unlikely to have children. Yet, Accutane is not tightly controlled like Thalidomide and Accutane is marketed to women of child bearing years despite its horrendous record of causing birth defects."

"If the FDA cannot or will not regulate Accutane, then it is imperative for the US Congress to act to protect the American public. The bottom line remains the safety of our citizens."

"The scope and depth of Accutane's serious adverse event reports compiled by the FDA are only a fraction of the actual number of deaths, birth defects and devastation caused by this drug. The true number of Accutane victims and their families are real, and once again the FDA has let us down!"

During this Congressional Hearing, the President and Chief Executive Officer of Hoffmann-La Roche, George B. Abercrombie, testified before the Committee. After giving various statements under oath about studies, marketing, clinical trials, and Roche's connections with entities down in Mexico, two members of the committee told Mr. Abercrombie that they did not believe his testimony, and that he had given the testimony in front everyone with a "straight face." Florida Congressman Peter Deutsch stated to Mr. Abercrombie during his questioning that "what you just said is not a truthful statement, you're beyond the straight face test, I'm sorry." Not a single member of the Congressional committee spoke in support of Hoffmann-La Roche. Also at this hearing, confidential papers were revealed showing that after the first Accutane Congressional Hearing held on December 15th, 2000, Roche employees were celebrating and shaking each other's hands because they were able to delay and prevent the authorities from implementing a registry for Accutane's psychiatric side effects.

In another Congressional statement titled *Supplemental Review of Accutane Safety Issues* Stupak talks about how, for decades, Roche has continually suppressed critical information about Accutane's mechanism of action and the biological mechanisms of vitamin A and retinoids. In the several quotes from his statement I've provided below, HLR stands for Hoffmann-La Roche,

"During a time when it took years to receive a new drug approval, in 1982 the FDA approved Accutane within 9 months. The FDA has reviewed the original application for Accutane and has

told committee members and staff that Accutane would never be approved by today's drug regulatory standards. The original new drug application trials showed that of the 523 people given Accutane in test studies only 89 were children and only 6 had a diagnosis of acne. The Accutane labeling is misleading 'in stating that efficacy for severe nodular acne was established in clinical trials, given the extremely small sample size.' Because Accutane has significant adverse effects associated with its use, it is to be prescribed only to patients with severe recalcitrant cystic acne. It is unknown whether these 6 children had severe cystic acne. Exhibits #1,2, and 3."

"The FDA's safety focus has been on the birth defects and not the psychiatric injuries caused by Accutane. In 1985, the first suicide attributed to Accutane was reported to the FDA. Dr. Huene, FDA Medical Officer, requested a review of the number of CNS [central nervous system] effects reported in patients on Accutane. These have included severe headaches, seizures, tremors, disorientation, numbness and parethesias, blurred vision, memory loss and behavioral changes other than depression. Exhibit #5."

"In 1987, Dr. Huene requested assistance with the 'difficulty of reviewing the adverse reaction reports associated with Accutane therapy……well over 3,000 adverse reaction reports…..(the number is probably approaching 4,000 by now)….. we find it impossible to deal with this volume of information coherently….' Without an additional full-time reviewer to '…..adequately collate, review and make recommendations' regarding all the adverse reaction reports associated with Accutane. Exhibit #5."

"In regard to psychiatric injuries, HLR's efforts have been to suppress adverse events reports and medical/scientific evidence. HLR withheld its own studies that shed light on Accutane's effect on the central nervous system. Further, HLR failed to submit safety precautions employed by other countries, provided 'junk science,' and denied any biological causation between Accutane and psychiatric injuries. The only consistent explanation of these psychiatric injuries put forth by HLR is to blame the patients for their psychiatric problems. Throughout the history of Accutane, HLR claims it does not know how Accutane works. Therefore, HLR cannot claim that Accutane does not cause psychiatric injuries. HLR cannot have it both ways. It is obvious HLR is more interested in protecting its profits than in finding the cause of psychiatric injuries in Accutane therapy. Exhibit #77, 78, and 79"

"HLR cannot claim that it was not aware of the requirement to inform the FDA of recent scientific and medical studies showing that Accutane, vitamin A, retinoids or retinoic acid affect the central nervous system. As part of its annual report to the FDA, HLR submits a list of medical studies and scientific research on Accutane therapy, vitamin A, retinoids, and retinoic acid. Some of these studies and research demonstrate a cause-effect relationship between Accutane therapy and psychiatric injuries. For example, some of these studies and research from as early as 1980 raise the concern of vitamin A toxicity from retinoid use affecting the central nervous system. Exhibit #51, 52, and 53"

"HLR will put out information they know is wrong and very little is done to correct it. For example, when Charles Bishop flew his airplane into the bank in Tampa and Accutane was mentioned as a possible cause in Bishop's behavior, HLR cranked up its PR machine. The

thought was planted that we would have to wait until the autopsy report to see if Accutane was present in Bishop's body. HLR knows full well that standard autopsies do not test for the presence of Accutane. As the FDA pointed out in an email, 'Given the bad news about the poor kid in Florida, it is even MORE urgent that we get the letter out to JAAD (Journal of the American Academy of Dermatology)…....The derms are being poisoned with absolute nonsense and it is downright dangerous in my book…...I know we can't compete with the Roche machine for their attention, but we have to try anyway!' Exhibit #101 and 102."

"In 1999, the FDA was so concerned about HLR's reporting and 'soft coding' of Accutane psychiatric injuries that they did a 'surprise' inspection of HLR's plant and its adverse events database. The inspection resulted in a Warning Letter from the FDA for not timely submitting adverse event reports for several years and failing to disclose over 2,000 more Accutane adverse event reports. Exhibit #91,92, and 93."

"As the June 25th, 2002 FDA states, "So….even if you make a VERY conservative guess at the number of waived cases, adding this up for just this ONE year exceeds the numbers derms have available on their radar since the drug was approved in 1982……As it stands right now, we do not even know how many such reports fall under each Body System. I am very concerned that someone 'outside' is going to get their hands on, and publish, the real numbers of psych reports obtained during the legal discovery processes no doubt going on……FDA is going to look pretty sad if someone else points out there are thousands more than we acknowledge publicly!!" Exhibit #42."

"At our December 11th, 2002 hearing, our colleague Ted Strickland picked up on the deadly spontaneous action caused by Accutane in young people when he asked, 'Is it possible that this medication has an effect, an action that results in spontaneous, impulsive, self-destructive behavior that is different from that which occurs from a clinical depression?'"

"The 'spontaneous action' mentioned by Congressman Strickland and testified to by the Turney and Benz family members at our December 11th, 2002 hearing separates Accutane caused psychiatric injuries from clinical depression. Even the dermatologist at the hearing testified that she could not predict when spontaneous events may occur in Accutane patients."

"In the case of Matthew Turney, age 16, he was alone for 10 minutes when he came home from school and shot himself. Matthew and his parents were watching for any signs of depression as they were aware that Accutane may cause psychosis, suicidal ideation, suicide attempts, and suicides. Yet his parents never saw signs of depression and are asking how do parents protect their children when there are no clues as to when the fatal 10 minutes can occur!" Exhibit #60"

"Micheal Benz was a 31 year old fire fighter who never had acne but was prescribed Accutane. A tri-athlete, Michael cried out for help from his physician and was told to come back on Monday. Micheal Benz drowned himself by weighting his body down with weight lifting plates. The investigation into his death showed that he had logged onto an Accutane website the weekend he died. As a fire fighter and an EMT, Michael Benz must have had some idea what was happening to him. Still, he could not resist the sudden urge to take his own life. Exhibit #61"

“A review of the suicide adverse event reports describes young people with no history of psychiatric problems taking their lives. There are reports of young people talking to their parents one minute and then hanging themselves the next minute. There are reports of young people who have fender bender accidents and when law enforcement arrives to discuss the accident with them, they leave to get their driver’s license and instead grab a gun and shoot themselves. Exhibit #62.”

“This aggressive behavior referred to as OIB or SIB (self-inflicted bodily harm) was referenced in a 1999 email where the Accutane Medical Review Officer remarked that “I gave up trying to track all psychiatric reports and just have the self-injurious behavior cases…..sorted into my ‘SIB” stack, which is sadly growing tall.” Exhibit # 63, 64, and 65.”

“This aggressive behavior seen in Accutane patients manifested itself not only in self-inflicted injuries but also in four murders and reported murderous ideation amongst Accutane patients. Exhibit #66.”

“Of course, HLR denied any causation between aggressive behavior and Accutane therapy. Finally, on October 30th, 2002 the FDA added ‘aggressive/violent behavior to the list of events that Accutane may cause.’ Exhibit #68.”

“As the FDA noted in its August 31st, 2000 email, ‘The population for whom Accutane is prescribed is overwhelmingly young and healthy. Accutane has been associated with many adverse events affecting nearly every organ system, and is a potent teratogen. Some of these adverse events are serious/life-threatening and the current labeling include a Black Box Warning, 11 additional Warnings, and 18 Precautions.’ Even with this growing list of Accutane warnings/precautions, patients and their families are never told of its hidden dangers. Exhibit #68.”

http://www.house.gov/stupak/accutane/p3_21.pdf

During a January 2003 interview with Jamie Kosar about the psychiatric side effects of Accutane, Bart Stupak had this to say when Kosar asked if there had been other types of brain damage or psychiatric injury such as anxiety and panic attacks associated with Accutane,

"Yes. It's there. It's all there. They're changing their labeling you know. And it wasn't clear yesterday and maybe we didn't do a good job on this part. They've had to change their label. The new label talks about ‘aggressive, violent behavior.’”

“The ‘depression’ that you see with this, if you want to use that word, is not your garden type depression that we all see. It's not that kind at all. It comes on [snaps fingers] like that. And it's a violent outburst. We didn't get into it yesterday because I had so many areas I could go. They talked about SIB's throughout the whole thing. ‘Self-inflicted bodily harm.’ These kids, there's one kid who set himself on fire and jumped off a cliff. He lived. He can't tell you today why he did it. An Accutane kid. He left a note that doesn't make any sense whatsoever. There's a service man that was taking Accutane. Came home. He was probably about twenty years old. He was in boot camp. He knew his parents would be gone. They would be home on Sunday. He came home

and ransacked the house looking for a gun to shoot himself. Couldn't find one, so instead, he took a big knife and started stabbing himself. And his buddies happened to come through the kitchen door and found him on the kitchen floor full of blood all over the place. And to this day he doesn't know why he did it. If he could've found a gun that day he would've killed himself."

At the end of this interview when Stupak was asked if there was anything he'd like to tell a parent or any young adult or teenager who was considering Accutane for their acne, he responded with,

"Don't do it. It's not worth the consequences. What is the benefit you're receiving clean skin. But, you may have a child who is forever scarred mentally, physically. We talked about the strokes yesterday. Young people dying of strokes. We talked about the heart attacks. We talked about the lymphoma. We talked about the acute pancreatitis. Even if you don't die from pancreatitis it's very painful. We talked about the hearing loss. There's vision problems. There are eighteen different warnings with this drug. Read them. And if you still think it's worth it, that's your decision. It's just not worth it."

The full interview can be found at the following links. Stupak gives an in-depth discussion about the disturbing patterns that are seen in Accutane's psychiatric side effects and how Roche has suppressed and twisted around the evidence.

"The implications are clear. Accutane is a very powerful drug that has been linked to suicides, birth defects and severe psychiatric/brain injuries. Either the FDA takes a more aggressive stance in managing and controlling ALL the risks associated with Accutane, or every day in this country our friends and loved ones will suffer severe consequences. Many of those consequences, some have argued (ie. brain injuries, severe birth defects), may even be a fate far worse than death."

Did Accutane Have a Role In the Death of Bart Stupak, Jr.?
Part 1
http://suicideandmentalhealthassociationinternational.org/acba.html
Part 2
http://suicideandmentalhealthassociationinternational.org/acba1.html

Stupak weighed in on the FDA's reluctance to take action in 2004.

"FDA must ensure that all health prescribers and patients receive education about all the effects of this drug, including psychiatric. The current voluntary informed consent forms must be made mandatory."

"The agency cannot continue to claim this drug is safe, while at the same time say Accutane may cause serious psychiatric events, including suicide. In fact, the FDA has evidence - animal studies and a new PET human brain scan study - which demonstrate that Accutane affects the brains of young people."

"This past month, I have spoken with three more families who have lost their sons to Accutane,

yet the FDA and the manufacturers of Accutane ignore this fact."

On October 24th, 2006, former patient Hans Peterson walked into the office of Chicago dermatologist Dr. David Cornbleet and stabbed him to death because the Accutane Cornbleet prescribed Hans caused him many permanent side effects including impotence. A year after the murder, Chicago police were tipped that Hans had fled the United States and obtained French citizenship down on the island of St. Martin located in the Caribbean. This is where he eventually turned himself in to French authorities and confessed to the crime, which under French Law, protected him from being sent back to the US to face trial. Here are a few articles about this story.

Man Surrenders In Murder Of Downtown Dermatologist, Suspect Allegedly Admitted To Revenge Killing
http://cbs2chicago.com/local/Dr.David.Cornbleet.2.339075.html

Confessed murderer's father talks about drug's effects
http://abclocal.go.com/wls/story?section=local&id=5697503

Accused Killer's Dad: Slain Doctor Partly To Blame
http://www.nbc5.com/news/14291306/detail.html

Murder suspect may have believed doctor made him impotent
http://www.beforeyoutakethatpill.com/papers/accutane.txt

Suspect in doctor's murder to be tried on island
http://abclocal.go.com/wls/story?section=local&id=5612206

Dateline NBC: In murder case, a French disconnection
http://www.msnbc.msn.com/id/23578261/

According to one of his final blogs on the Ro/Accutane Action Group forum, before turning himself in, Hans wrote,

“Justice will not be found through the legal system. Would taking some of their money even be justice? Their lives would go on, just with a little less money. Our lives will never be the same.”

The Cornbleet family has set up a website to create more awareness about this case and to generate a following for the extradition of Hans Peterson back to the United States. http://drdavidcornbleet.blogspot.com/ In his thesis titled “A Tragedy with Multiple Victims and Multiple Villains” Hans Peterson’s father, Dr. Thomas Peterson writes,

“Hans believed that it was Accutane that caused him so much pain and anguish. Since the murder, many, many blogs that Hans wrote about how Accutane ruined his life have been discovered. Reading the blogs is like reading the secret diary of a young man who is going mad. In fact, the Accutane had caused Hans to become psychotic, a permanent condition that developed in the first two weeks after ingesting the drug. The effects do not go away, there is no

antidote, and Hans, an exceptionally intelligent man, knew that his life was over. He blamed Dr. Cornbleet and eventually decided that vigilante justice was the only justice possible."

"The FDA has allowed Roche to continue to market this drug by putting more responsibility on the prescribing doctor. Unfortunately, not all doctors are responsible."

"In 1997, Liam Grant from Ireland committed suicide while taking Accutane. His father (Liam Grant Sr.) was wealthy and funded research on the physical effects of Accutane on the brain. J. Douglas Bremner, Professor of Psychiatry and Radiology and Director of the Emory University Medical School Clinical Neuroscience Research Unit has done this research [Am J Psychiatry 2005; 162:983-991] and it is showing damage to the emotional part of the brain from Accutane through PET scans. He asked Roche to provide him with Accutane to help with further research. They refused. They do not want any research to show that Accutane damages the brain because that would be detrimental to their future legal cases. Their defense is that there is no scientific evidence of any damage, and they dismiss these cases of psychosis and suicide as people who were going to go insane anyway."

"In his book, *The Lucifer Effect,* renowned social psychologist Phillip Zimbardo explores the "process of transformation at work when good or ordinary people do bad or evil things. Professor Zimbardo discusses the power of the System, (the 'big picture…big power') to create a situation in which evil triumphs over good. He calls this phenomenon, 'The Lucifer Effect.' America's health care system is now so corrupted by the millions of dollars being fed into it by big pharmaceutical companies that, arguably, the system is creating unknown numbers of situations ripe for the Lucifer Effect to prevail. Accutane is just one of an unknown number of drugs still on the market because Big Pharma is putting millions of dollars into Congress, the overseers of our Health Care System."

"When Roche's company's own safety experts recommended in 1997 changing the U.S. label on Accutane to reflect the evidence that the drug 'probably caused' depression and other psychiatric illnesses in some patients, the marketing department warned that such a warning would impact the marketing strategy and profits (estimated at over $700 million)."

"Accutane is Roche's number one selling product. Roche refuses to supply information on the adverse reaction reports they receive."

"The FDA has implemented programs; including writing letters warning prescribing physicians to have patients sign an 'Informed Consent' form. Roche negotiated to make this a voluntary, rather than a mandatory, form."

"According to Professor Zimbardo, 'Powerful Systems Exert Pervasive Top-Down Dominance' Big Pharmaceutical's million of dollars are at the top of the United States Health Care System. It is this system that has created 'Multiple Victims and Multiple Villians.' There is plenty of blame to go around in the Peterson/Cornbleet tragedy."

A Tragedy with Multiple Victims and Multiple Villains
http://drtompeterson.blogspot.com/

Another recent murder involving Accutane
Monroeville Man to Stand Trial in Fatal Cheerleader Stabbing
http://www.foxnews.com/story/0,2933,296873,00.html

In her article titled "Roche puts Accutane profits over Lives of Consumers" journalist Evelyn Pringle writes,

"In 1985, Accutane's package insert directed at doctors first mentioned reports of depression in patients taking the acne drug, which means that more than 20 years ago, Hoffmann-La Roche at least suspected there might be a risk of depression and suicide by persons taking the drug. However, Roche's financial records show that the company is not about to let a little thing like the death of its customers get in the way of corporate profits, because the drug is still a best seller and young people with no history of depression who take it are still killing themselves."

"And once again, according to BBC News, 'Roche insists there is no proven relationship between the drug and depression.' Roche's comments to the BBC are clearly dishonest considering that in 1986, doctors were notified that Accutane users who became depressed saw their depression lift when they stopped taking the drug but return when they were placed back on the medication. Doctors were also informed that simply stopping Accutane therapy might not be sufficient to treat the depression and that follow up on the depression might be necessary."

"Public health officials had been voicing concerns about patients committing suicide while on Accutane for well over a decade. For instance, a 1998 memo from the FDA's medical officer in charge of Accutane states: 'Given all the pieces of evidence available, it is difficult to avoid the conclusion that Accutane can adversely affect the adult human brain in clinically significant ways and that Accutane use is associated with severe psychiatric disease in some patients.' The memo recommends 'active consideration of removal of Accutane from the market.' But instead of removing the drug from the market, on February 25th, 1998, the FDA required Roche to add the following bold-face warning to drug's physician package insert: 'WARNINGS - Psychiatric Disorders: Accutane may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts and suicide. Discontinuation of Accutane therapy may be insufficient; further evaluation may be necessary. No mechanism of action has been established for these events. Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.'"

"In perverse twist of logic, in the same year, Roche began actively marketing Accutane as a treatment for depression, under the theory that it could help people who were suffering from depression due to poor self-image as a result of acne. On March 5th, 1998, Roche received a letter from the FDA stating that such promotion was false and misleading, and that Accutane had never been approved for the treatment of depression, and that in fact, just the opposite was true. The letter stated in relevant part: 'Roche ... has not systematically studied the ability of Accutane to modify or prevent such illnesses as depression and has presented no basis for asserting that Accutane is effective in improving the psychosocial and emotional well-being of such patients. This claim is particularly troublesome in light of information recently presented in a Dear Doctor letter, that Accutane may cause depression, psychosis, and rarely, suicidal ideation, suicide

attempts and suicide.'"

"In July of 1998, the FDA becomes aware that French authorities had already required the addition of an Accutane 'suicide attempt' warning in 1997, of the 1992-94 French study associating Accutane with depression, and of Roche's failure to disclose this information to the agency."

Roche puts Accutane profits over Lives of Consumers
http://www.lawyersandsettlements.com/articles/00299/Accutane_Profits.html

"Unfortunately hundreds of parents already know that Accutane can cause some teenagers to commit suicide, but new evidence of a link between the acne drug and depression in the journal, Neuropsychopharmacology, will hopefully put an end to the years of claims by Hoffmann-La Roche that its drug is not responsible for the suicides. The drug maker's explanation for the sudden unexpected suicides among teens on Accutane has always been to say that teens were likely to be depressed due to their acne."

"For years, Roche has denied that Accutane causes depression and suicide and internal FDA documents show the agency was aware of these risks almost since the drug came on the market."

"The new scientific evidence will hopefully put to rest the ridiculous claim that teens on Accutane commit suicide because they have acne. However, the news is not likely to offer much solace to all the grieving parents. According to the Guardian article, last year in the UK, Jason Spiller, 16, killed himself after starting the drug in April 2005. The previous year, David Roberts, a 20-year-old, killed himself, and in 1997, Seumas Todd, 20, son of the actor Richard Todd, killed himself while taking the drug."

"Documents introduced at a December 11th, 2002, Congressional hearing by the House Oversight and Investigation Subcommittee, revealed a 1998 letter to the FDA from an official at the CDC, that compares Accutane to the infamous cancer and leprosy drug Thalidomide, a well known cause of birth defects, stating, 'we simply need to remove the drug from the market.' The committee also discussed the unnecessary health problems caused by the high rate of 'off-label' use of Accutane by individuals who did not have severe cystic acne, the only condition the drug is FDA approved to treat. Dr Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, testified that, 'A proportion of people treated with this drug in the last decade had mild acne and should've been treated with other drugs.' In fact at the time, the off-label use of Accutane was so prevalent, that some experts estimated that the improper use was close to 90% among women."

"To date, other serious side effects associated with Accutane include problems with the pancreas, liver, stomach, bones, muscles, hearing, vision, allergic reactions, blood sugar, or red and white blood cells. According to the iPLEDGE web site, the most common side effects include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds."

“The FDA needs to yank this drug off the market once and for all. Weighed against its endless list of serious side effects, there is no justifiable reason to keep it on the market. Let the drug companies develop a new drug to treat acne.”

FDA Needs To Ban Accutane
http://usa.mediamonitors.net/content/view/full/35718
http://www.lawyersandsettlements.com/articles/00334/Accutane_Ban.html

During the past two decades many Accutane patient support groups and activist groups have emerged all around the world. In 2001, Andrew Hart from Sydney, Australia created the Australian Roaccutane Survivors Group (Roaccutane is Accutane outside the USA). On their website, Hart describes Accutane’s resemblance to vitamin A toxicity, and the many chronic latent symptoms experienced by former Accutane users,

"It is the belief of the Australian Roaccutane Survivors Group (ARSG) that many Australians are suffering adversely both in the short- and long-term from the acne drug Roaccutane. Doctors are still failing to adequately warn patients of the currently known short-term risks. More concerning, many patients are complaining about long-term side effects that may appear years after finishing therapy and which may last for up to 15 years post-therapy. These side effects are not being related to a patient's previous ingestion of Roaccutane, especially since the patient is unlikely to consult the same dermatologist for such complaints and despite the fact that in many cases, the patients’ skin/eyes/hair are still very dry and continue to exhibit a sensitivity to vitamin A ingestion. Even worse, the majority of patients who receive Roaccutane have mild acne which means the majority of Roaccutane is prescribed outside of the strict licensing limitations which restrict it to the most severe disfiguring cases of acne. The ARSG believes that most doctors and health authorities are yet to appreciate the gravity of this situation.

The side effects reported by people in the years post -therapy include those characteristic of hypervitaminosis A; (vitamin A toxicity) and include:

1.Neurological Toxicity: chronic fatigue, visual disturbances, headaches, weakness, changes in coordination, vertigo, chronic neuropathic pain, nausea, psychiatric disturbances (psychosis, schizophrenia, depression, suicide), confusion, irritability, lack of concentration, memory difficulties, depressed libido, male impotence, insomnia, tinnitus.

2. Musculoskeletal Problems: joint pain, back pain, bone pain and tenderness, muscle aches and pains, stiffness, decreased flexibility and range of motion, bone spurs.

3. Mucocutaneous Toxicity: dry and peeling skin/eyes/hair/lips/nose, hair loss, hair thinning, hair changes, rashes, dermatitis, eczema, chronic skin/eye/lip infections.

4. Ocular Problems: dry eyes, conjunctivitis, cataracts, blurred vision, double vision, optic neuritis, papilledema, changes in night vision.

5. Gastrointestinal Problems: loss of appetite, weight loss, irritable bowel syndrome, Crohn's disease, Ulcerative colitis, pancreatitis, nausea, non-specific gastrointestinal changes and inflammatory bowel diseases.

6. Hormonal and Sexual Dysfunction: abnormal menstruation (women), impotence (men), painful intercourse.

These side effects are now accepted as short-term risks of Roaccutane therapy. Patients are not being warned however, that many of these symptoms may persist up to 15 years or more post-therapy."

http://www.drugawareness.org/Archives/1stQtr_2003/record0025.html

David Chow, chairman of the Ro/Accutane Action Group in the UK, has suffered for several years from "a multiplicity of long-term side effects" and a constantly painful lip condition called exfoliative cheilitis. His full story can be found at the Ro/Accutane Action Group Forum. http://ragforum.freeforums.org/index.php I've included a brief summary of his story below,

"In 1994, at the age of 17, I took a course of isotretinoin (Roaccutane) for mild acne, a decision I have regretted ever since. In my case, the side-effect of dry lips has progressed to persistent exfoliative cheilitis. My lips are constantly painful, fissured, swollen and prone to recurrent infections, making everyday activities such as eating, drinking and even smiling (though I don't have much to smile about these days) a daily ordeal. My ability to speak for any length of time is so severely impaired that I am unable to work. I have also developed central nervous system problems similar to those associated with Roaccutane. As a result of a report submitted by me to the UK's Medicines Control Agency, cheilitis now appears as a side-effect on all prescribing information sheets. However, this possible side-effect has been known and listed for some 20 years in the US. Such omissions are not uncommon. Another long-known side-effect I have - blepharitis (inflammation of the eyelids) - is mentioned nowhere in the documentation. It makes me wonder what the MCA is for. More pertinently, Roaccutane is being prescribed outside of its licence, as it was originally intended for only those who had the most severe, recalcitrant forms of cystic nodular acne. Studies have shown that the extent of off-label prescribing may be as high as 80 percent. You may be familiar with the association between isotretinoin therapy and suicide, consistently denied by Roche, the manufacturer of Roaccutane, and the medical dermatological establishment. I can't help but wonder about the volume of adverse reaction reports they seem to be ignoring. Since attending a meeting last December in London, organized by Mr. Liam Grant, whose son committed suicide after a course of Roaccutane, I have become aware of many others whose lives have been damaged by isotretinoin therapy. I am seeking a dermatologist who would be prepared to review my case as well as others in the hope that we might be able to seek some redress from Roche for our years of pain and impaired prospects. David Chow, Chairman of the Accutane/ Roaccutane Action Group (UK)"
www.accutaneaction.com and www.ragforum.com (this is the web address to the old forum)

Why weren't we told about this acne drug
http://www.healthy.net/scr/article.asp?Id=3401

Roche has known since the 1970's that Accutane causes side effects in 100 % of everyone who takes it. Everybody gets dry/cracked/fissuring lips while on it, which is a definitive sign of vitamin A toxicity. Dermatologists tell their patients that they need to endure the most common side effects of Accutane (dry skin, dry lips, photosensitivity, dry eyes) in order to gain a

therapeutic acne reducing effect. Do these patients realize that these specific symptoms they're experiencing are due to the vitamin A toxicity syndrome caused by the Accutane pills they are taking? Dermatologists usually don't disclose to their patients that they are basically poisoning their body with vitamin A in order to reduce their acne, but a few dermatologists really do tell it how it is by saying that Accutane causes "controlled vitamin A poisoning" as illustrated by the following quote from a dermatologist's website about Accutane,

"I've always tried to explain it as controlled vitamin A poisoning, as the potential side effects are similar to those that would occur if you took far too much oral vitamin A."

https://www.dermadoctor.com/pages/newsletter96.asp?WID=%7B8D162C43-114F-491A-A6F4-4E4057D8F8C3%7D

It has been estimated that up to 90 % of all Accutane prescriptions are going to people with mild to moderate acne. All you have to do is look at the sales of Accutane, compare it to the small percentage of people with severe cystic acne, and it becomes obvious. Making matters worse, the dermatologists are getting all of their information from Roche drug sales reps and are not conducting any due-diligence of their own, which is why some of the blame has to be placed on them. These doctors are using a powerful drug that can inflict chronic latent severe side effects upon teenagers and young adults who have their entire lives ahead of them.

Initially, Accutane was only meant to be prescribed for severe cystic acne, but it is still debatable whether or not the drug should even be used for this type of severe acne because the patient might end up with side effects that are far worse than severe cystic acne. By prescribing Accutane for "off-label" uses such as mild and moderate cases of acne, dermatologists have radically deviated from its strict prescribing guidelines. This is definitely good for business because it increases the sales of the drug over 2000 percent, but not so good for the health of millions of innocent and naive teenagers who have been exposed. It is clear that the first dictum of the practice of medicine, to "first do no harm," is being ignored. One thing becomes very obvious when you examine the whole Accutane situation. Dermatologists only care about clear skin, your health and bodily functions mean absolutely nothing to them.

We're talking about an acne medication. Most people rightfully think that acne medications are all safe because acne itself is a benign non-life-threatening condition. This is logically how it's supposed to be, but Roche, the FDA, and even some dermatologists have done an excellent job of deceiving everybody. A few dermatologists are much more ethical when it comes to prescribing Accutane and recognizing its dangers. In 1983, Dr. Frank Yoder, one of the two doctors who originally discovered Accutane to be an effective acne medication, wrote a letter to the American Medical Association stating,

"I wish to express my concern and anxiety over the potential tragedy that might arise from abuse and misuse of Accutane…the potential toxicity of this drug has been seriously under-emphasized." [Isoretinoin: A Word of Caution 249 JAMA 350 (1983)]

The risks of taking Accutane are so great that the FDA has taken the remarkable step of requiring each prescription to come with a medication guide that explains the side effects in non-technical

language. But the Accutane Medication Guide didn't come out until 2001, which was two decades too late for thousands of people who had been inflicted with severe side effects. Even though the medication guide was released in 2001, not all dermatologists and pharmacists have been handing it out to everybody. It contains a laundry list of warnings such as,

"Stomach area (abdomen) problems. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your doctor if you get:
-severe stomach, chest or bowel pain
-trouble swallowing or painful swallowing
-new or worsening heartburn
-diarrhea
-rectal bleeding
-yellowing of your skin or eyes
-dark urine"

"Vision problems. Accutane may affect your ability to see in the dark. This condition usually clears up after you stop taking Accutane, but it may be permanent. Other serious eye effects can occur. Stop taking Accutane and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant."

"Hearing Problems. Some people taking isotretinoin have developed hearing problems. It is possible that hearing loss can be permanent. Stop using Isotretinoin and call your prescriber if your hearing gets worse or if you have ringing in your ears."

"Spontaneous reports of osteoporosis, osteopenia, bone fractures, delayed healing of bone fractures, muscle weakness, and calcifications of tendons and ligaments have been seen in the Accutane population. There are reports that some patients had stunted growth after taking Accutane for acne as directed."

Contrary to popular belief, the human body doesn't completely stop growing until the age of 21, sometimes later. It was known decades before Accutane was released onto the market that vitamin A toxicity can cause premature growth plate closure in children and adolescents, which is why nobody should be allowed to take Accutane if they're under the age of 21, but dermatologists still routinely prescribe it to teenagers as young as 13, so the derms have apparently never gotten wind of this side effect because they tend to get their information from Roche and don't ever think for themselves. The testimonial I've quoted below illustrates how a family discovered the growth plate closure problem the hard way. It was posted on a Yahoo Geocities Accutane message board way back on December 12th, 1999.

"It troubles me greatly to see that young growing teenagers are being given this drug. I have two boys that had their growth plates rapidly closed by this drug. Roche lists as its first side effect in their South African package insert: premature epiphyseal plate closure. Medline has a pediatric precaution stating that Accutane is absolutely contraindicated in ages 0-16 due to premature epiphyseal plate closure. The side effects are much more powerful in a growing body. My boys

bones never finished spreading and maturing. They also have premature arthritis. This drug robbed them of all their dreams as we are a very tall family and they were never told it would stop their growth. We finally got the charts from the doctor and he wrote that he old us of growth retardation. My boys would have never taken this drug if they had been told the truth. They did not have anything but pimples. Unfortunately for us, we believed the doctor. Even in the US package insert it only says that premature epiphyseal closure is suggestive. How can it be known in one country and suggestive in another. Someone is not telling the truth. Most kids don't even realize that this drug stopped them from growing. We had been tracking our sons height and have x-rays before, during and after on our 14 year old. His bones were completely sealed shut. My boys are now 17 & 19 and they are still the same size as they were at 14 & 15. Why aren't the doctors telling the truth$$$"

http://www.geocities.com/HotSprings/Spa/2738/january00.html

The research document titled "Health risks related to high intake of performed retinol in the Nordic countries" contains an abundance of information about retinol toxicity (AKA vitamin A toxicity or hypervitaminosis A) and its deleterious effects of the musculoskeletal system. Below, I've listed a few important quotes.

"Synthetic retinoids are widely used in the treatment of skin diseases and some cancers. Their toxic effects mimic those of hypervitaminosis A and include musculoskeletal symptoms. The patients may complain of bone and joint pain, stiffness, and/or impairment of function. Cortical hyperostoses and ligamentous calcification are the most frequently reported skeletal changes (DiGiovanna et al., 1986; Pittsley and Yoder, 1983). In children, premature epiphyseal closure has been described following high dose retinoid therapy (Milstone et al., 1982). Of higher importance is the concern that long-term therapy with synthetic retinoids might induce osteoporosis. Animal studies have predicted development of osteoporosis as a dose-dependent toxic effect (reviewed in Teelmann 1989). In man, synthetic retinoids have been shown to alter bone turnover (Decensi et al., 1999; Kindmark et al., 1998). Decreased bone mineral density has been found in retinoid treated patients compared to age- matched controls (DiGiovanna et al., 1995; Leachman et al., 1999; Okada et al., 1994). The risk of undesirable skeletal effects is of course dependent on the choice of drug, dosage, and duration of treatment, but it nevertheless clearly exists, which the clinical guidelines advising caution and careful monitoring of bone symptoms during long-term therapy witness (Glover et al., 1987; Nesher and Zuckner, 1995)."

"As described in chapter 5, the symptoms of retinol toxicity include hypercalcaemia, bone and joint pain, as well as skeletal abnormalities, clearly indicating that high doses of retinol interferes with calcium and bone metabolism. The mechanisms of these effects are not well understood, but as will be discussed below are likely to be complex. However, although these toxic effects have been known for decades, the effect of physiological ranges of retinol intake on skeletal integrity has not received much attention."

"Bone, along with the skin and the developing embryo, are some of the targets for retinol activity and these tissues appear to be more susceptible to deleterious effects than others (Teelmann, 1989)"

“A large body of evidence documents that large doses of retinol have undesirable effects on the skeleton. It is generally accepted that toxicity is associated with consumption of retinol, whereas carotenoids in foods are not known to be toxic in healthy persons.”

“Bone alterations are the most prominent and well-described effect in toxicology studies in animal models. A striking feature is the consistent occurrence of spontaneous fractures. In a recent review, Binkley and Krueger (2000) note that searching Medline, they found no other compounds reported to produce spontaneous fractures. Other manifestations include severe osteoporosis, thinning of the bone, retardation of growth, exostosis, and premature growth-plate closure (Carroll et al., 1997; Niemann and Obbink, 1954; Tang et al., 1985).”

“As described in chapter 5, chronic hypervitaminosis A produces a broad spectrum of symptoms from a variety of organ systems. The clinical picture may be quite diversified and non-specific. In many cases, the correct diagnosis is difficult and may not be made for months or even years. Skeletal symptoms are a major feature of chronic retinol intoxication and they have been described in a number of case reports. They include general muscular and skeletal discomfort, severe bone pain, especially in the long tubular bones, tender swellings, disability and limitation of motion (Caffey, 1950; Frame et al., 1974; Romero et al., 1996). Common clinical findings are hypercalcaemia, hyperostosis and ligamentous calcification (Ragavan et al., 1982). Other extra-skeletal calcifications, like nephrocalcinosis, have been described (Frame et al., 1974). At a later stage, demineralisation of bones or osteoporosis may be seen (Bartolozzi et al., 1967; Frame et al., 1974; Gerber et al., 1954). In children, growth retardation and premature epiphyseal closure may occur (Pease, 1962). In bone biopsies taken from subjects intoxicated with retinol, an increase in extent of the bone resorbing surfaces was seen, while the formation surfaces were on the low side of the normal range (Jowsey and Riggs, 1968). The presence of enlarged osteocyte lacunae, so-called ‘osteolysis,’ is another characteristic of retinol intoxication, that has been described in both humans (Jowsey and Riggs, 1968) and animals (Belanger and Clark, 1967). These alterations are compatible with loss of bone tissue.”

Health risks related to high intake of performed retinol in the Nordic countries
http://folk.uio.no/runeb/pdf%20filer/Vitamin%20A%20toxicity.PDF

Roche’s track record for creating dangerous drugs extends beyond Accutane. Take Lariam for example, which is used to prevent Malaria. Just like Accutane, Lariam has been linked to several cases of permanent brain damage, severe psychiatric side effects, suicides, and murders. Roche is also responsible for developing the date-rape drug Rohypnol, and the dangerously addictive tranquilizer Valium. With all this in mind, it becomes clear that creating deadly drugs with mind-altering side effects is their forte.

"service members have been diagnosed with permanent brainstem and vestibular damage from being given this drug despite the fact that alternative drugs might have been chosen to prevent infection."

Senator: GIs Got Brain Damage From Malaria Drug
http://www.yourlawyer.com/articles/read/8121

“A San Antonio couple has filed suit in New Jersey state court charging drug giant Hoffmann-La Roche with ‘knowingly withholding or misrepresenting information’ about side effects of its anti-malaria drug called Lariam.”

“Lariam also made news this summer, after three Fort Bragg Special Forces soldiers given the drug during deployment in Afghanistan returned home and allegedly killed their wives. Two also committed suicide.”

Suit: Lariam drugmaker hid side effects
http://www.aaconsult.com/lariam/lariam_news_31.html

“Manofsky is a decorated serviceman, a weapons targeting specialist, a naval aviator who has also boated, skied and dived. Now he can't do any of those things. Manofsky's problems began when he was sent to Kuwait in the run-up to the war in Iraq. Like thousands of others, he was given a drug called Lariam to prevent malaria. He got sick. He couldn't sleep and he started having psychological problems. ‘I lost it. I literally went nuts. I was talking to myself. I was talking to myself in the chow. I was waking up mad. I would go to bed mad. Using my hands to talk to myself.’ The panic attacks became so acute we had to rush him to the emergency hospital five different times. He also went into seizures where his whole body was convulsing.”

Harmful Side Effects of Lariam
http://transcripts.cnn.com/TRANSCRIPTS/0405/26/i_ins.00.html

“’I've chased bad guys all around the world; been beat up, shot at; developed dengue fever and encephalitis’ says Jim Prietsch, who has worked as a Washington, D.C., police officer and protected U.S. and foreign leaders for the State Department and the World Bank. Nothing, he adds, was as bad as what happened two years ago on back-to-back trips to Indonesia and Africa. ‘I started to have panic attacks, nightmares, hallucinations, by the time I got to Africa, I thought I was going crazy. Problems got worse and worse. Finally, I had seizures like someone was reaching inside my brain and flipping it upside down. I had no idea what was going on.’ Not until a colleague from Europe saw the white pill Prietsch took once a week ‘He told me, 'That's your problem - that stuff is poison.’’ An infectious-disease specialist later confirmed that the cause of Prietsch's problems was most likely the pills he'd been taking: mefloquine.”

Lariam’s Legacy
http://home.att.net/~kjo/lariam2.htm

“Seven U.S. servicemembers have been diagnosed with inner ear damage ‘most likely’ caused by use of the anti-malaria drug Lariam, said a Navy surgeon treating them. Use of the drug is the only factor the seven members have in common, he said.”

“’Lariam studies have indicated that Lariam can damage the vessels and nerves of the brain, and the inner ear is subject to that same damage because it is part of the brain,’ said Hoffer, an ear, nose and throat surgeon who has practiced in the field for 10 years.”

7 servicemembers ‘likely’ ill from malaria drug

http://www.estripes.com/article.asp?section=104&article=21624&archive=true

Hoffmann-La Roche is part of a leading international health care company called "The Roche Group" with its principal businesses in pharmaceuticals, diagnostics and vitamins. This group is made up of many subsidiaries, they are the seventh largest pharmaceutical company in the world and are active in more than 150 countries. The Roche Group is well known all throughout the legal system because of their long-standing track record with regards to both civil and criminal activity. In 1999 Hoffmann-La Roche was named the top corporate criminal by the publication, Multinational Monitor, after they pleaded guilty and paid the largest criminal fine in history, $500 million to the American Department of Justice, $462 million to the EU, fines in several other countries, plus a 10 billion dollar settlement to creditors and suppliers they had defrauded in the US, EU and most other countries where they were selling vitamins. This happened after they were caught perpetuating a vitamin conspiracy/cartel where they collaborated to artificially inflate the price of food fortifying vitamins in the United States and all over the world for over a decade. FBI and EU documentation on this fraud showed an extraordinary level of corruption, lies, and misrepresentations made by Roche personnel at all levels of the organization, from its senior board of directors in Basal, Switzerland, through the separate Roche board of directors in each of the countries where Roche was conducting and perpetuating the fraud. Several of Roche's corporate executives were sentenced to prison for their roles in the vitamin cartel. United States Attorney General Janet Reno stated about the vitamin cartel,

"On a daily bases for the past 10 years, every American consumer paid to eat and drink or use a product whose price was artificially inflated. Day by day, consumers took a hit in their wallet so that these co-conspirators could reap hundreds of millions of dollars in additional revenue."

She went on to state that,

"This cartel was truly extraordinary. It lasted almost a decade and involved a highly sophisticated and elaborate conspiracy to control everything about the sale of these products. These companies fixed the price; they allocated sales volumes; they allocated customers; and in the United States they even rigged bids to make absolutely sure the cartel would work. The conspirators actually held "annual meetings" to fix prices and to carve up world markets, as well as frequent follow-up meetings to ensure compliance with their illegal scheme. The enormous effort that went into maintaining this conspiracy reflects the magnitude of the illegal revenues it generated as well as the harm it inflicted on the American economy."

"…Indeed, the members of the vitamin cartel, including Hoffmann-La Roche, continued to meet and carry out their global agreement even while Hoffmann-La Roche was being investigated, prosecuted, and fined $14m in March 1997 for participating in the citric acid cartel."

"The vitamin cartel was led by the top management at some of the world's largest corporations, including one company, F. Hoffmann-La Roche - which continued to engage in the vitamin conspiracy even as it was pleading guilty and paying a fine for its participation in the citric acid conspiracy….some senior executives of this mult-national firm knew about the firm's participation in international cartels in two industries. When the firm's illegal activities were uncovered in one industry, and the firm had to plead guilty and pay millions of dollars in fines,

those executives could have and should have terminated the firm's cartel activities in the second (and larger) industry. Instead, those executives orchestrated false statements to enforcement authorities, took steps to further conceal the firm's illegal activities, and continued to lead the world's other producers in a global cartel."

http://www.accutaneaction.com/Frauds/roche_finc_frauds.html

The Ro/Accutane Action Group states on their website,

"The vitamin cartel was described by the US Attorney General as the most pervasive and harmful criminal antitrust conspiracy ever uncovered, and Roche agreed to pay the largest fine in criminal history because it was caught flagrantly violating the law."

U.S. Outlines How Makers of Vitamins Fixed Global Prices
http://www.nd.edu/~mgrecon/datafiles/articles/vitamins.html

"Investigators were said to have been particularly angry at the executive, Kuno Sommer, because he had lied about the existence of the vitamin cartel and his role following Roche's guilty plea in another price-fixing case two years ago. In that case, involving citric acid, Roche paid a $14 million fine and promised to cooperate with investigators. Dr. Sommer, who had previously lived in New Jersey when he served as North American regional manager for Roche, denied in a 1997 interview with investigators that there was a vitamin cartel and said he was not aware of any meetings or conversations involving price-fixing in that market, according to court papers filed by the Government Thursday that are part of his plea agreement. In fact, at that time he was still playing an important role in setting vitamin prices and allocating market share, according to a plea agreement filed on his behalf Thursday in Federal court in Dallas. While Justice Department officials said Dr. Sommer was not the highest-level executive who knew about the conspiracy and cover-up, they did not say who might be prosecuted next. Among the executives who did not receive immunity in the deal reached with Roche were Roland Bronnimann, president of the Vitamins and Fine Chemicals division, and Andreas Hauri, a former executive vice president and head of global marketing."

"At a news conference here to announce the initial results of the investigation, Attorney General Reno and other senior officials described a global conspiracy to fix vitamin prices. They said one Swiss executive had agreed to return to the United States to serve a jail sentence, although he was not the highest-ranking official involved in the scheme. At least seven other executives remained under investigation."

Firms Admit To Price Fixing
http://www.lubbockonline.com/stories/052199/bus_0521990021.shtml

"Two giant foreign companies agreed Thursday to pay $725 million in fines for plotting to raise and fix the prices of vitamins used in virtually every American home and added to bread, milk and breakfast cereal. The $500 million fine to be paid by F. Hoffmann-La Roche Ltd., a Swiss pharmaceutical company, is the largest federal criminal fine ever imposed in any type of case, Attorney General Janet Reno told a news conference. A German firm, BASF AG, agreed to pay

a $225 million fine for its role in the conspiracy to increase vitamin prices in the United States and around the world. Both companies pleaded guilty in U.S. District Court in Dallas."

The New York Times: Tearing Down The Facade of 'Vitamins Inc.'
http://query.nytimes.com/gst/fullpage.html?res=9900E1DB1131F933A25753C1A96F958260&sec=health&spon=&pagewanted=all

In his book titled *Why Animals Don't Get Hearth Attacks - But People Do*, Dr. Matthias Rath, M.D. described Roche's vitamin cartel.

"By the turn of the century, the world's largest pharmaceutical and nutritional companies, including Hoffmann-La Roche, BASF, Rhone-Poulenc, Archer Daniels Midland (ADM), Takeda and other multinational corporations, had admitted to forming a so-called "vitamin cartel" to conduct criminal price-fixing for vitamin raw materials. Hundreds of millions of people worldwide were defrauded for almost a decade and had to pay artificially high prices for vitamins and certain other essential nutrients. The U.S. Justice Department declared that this vitamin cartel was the largest cartel ever discovered and named it an 'economic conspiracy.'"

"Hoffmann-La Roche apparently invited BASF, Rhone-Poulenc, Takeda and other manufacturers of vitamin raw materials to engage in criminal price-fixing on a global level. The fraudulent profits these companies made from their criminal practices may have reached hundreds of billions of dollars over the past 10 years. Compared to that, the fines these companies had to pay were insignificant."

"Not only should governments have sued these companies for the damage they had done, but above all, consumers world-wide should have filed class action lawsuits against them. These companies have harmed millions of people twice: First, they knowingly refused to promote and disseminate lifesaving information about the use of vitamins for the prevention of heart disease, thereby causing millions of heart disease patients to die unnecessarily over the past 10 years. Second, they caused financial damage to hundreds of millions of people – literally every vitamin consumer on earth."

"My correspondence with Hoffmann-La Roche executives also proves the statements they and others made that the corporate executives did not know about these criminal activities were lies. The opposite is true: These corporate executives not only knew about these crimes, they were the organizers. The executives responsible for these crimes should be prosecuted and held responsible for their actions."

"While that may take time, one benefit is already here today. All these companies have pleaded guilty to criminal activities. Thus, everyone can describe these companies and their executives for what they are – criminals who distinguish themselves from a street robber only by the magnitude of their crimes."

Scribd.com Why Animals Don't Get Hearth Attacks - But People Do
http://www.scribd.com/doc/3859811/Why-Animals-Dont-Get-Heart-Attacks-but-People-Do

Over the past 10 years, several anti-Accutane forums and posts have been closed down as a result of legal threats against the servers by you know who. But today the evidence of all the dangerous side effects is so overwhelming and indisputable Roche can't get away with launching these types of legal threats anymore. Throughout the 80's and 90's, Roche settled a countless number of severe side effects cases out of court and out of the public eye with gagging clauses. Under the terms of the settlement, the victims could not come forward to tell their story or share it with anyone. This is one of the tactics used by Roche to keep the most horrible Accutane side effects and evidence continuously suppressed over a long period of time. In "Babies, Blemishes and FDA: A History of Accutane Regulation in the United States" Julia Green from Harvard Law School writes,

"Out of the spotlight, Hoffmann-La Roche continued to grapple with the repercussions of Accutane related birth defects. By the mid 1990's, Accutane had earned the company a significant list of enemies, many of whom were looking to draw blood. Frank Yoder, in some ways a patron Saint of Hoffmann-La Roche—after all, his 1976 discovery had resulted in a tremendous money maker for the company—had spent the past fifteen years insulting Roche in the Washington Post. A subset of the plaintiff's bar called the Accutane Litigation Group had also been chipping away at Hoffmann-La Roche. The company had settled a number of expensive lawsuits. But each time documents were sealed, which meant new plaintiffs would have to start from scratch. The plaintiff's bar had become convinced that Hoffmann-La Roche had acted recklessly—something which might entitle clients to steep punitive damages."

http://leda.law.harvard.edu/leda/data/472/Green.html

Roche has never disclosed the total amount of money they've spent settling Accutane litigation cases. In 1995, a medical student launched a legal campaign to sue Roche for over $10 million. The lawsuit was later settled privately out of court, the details of this story can be read at the following link,

http://www.accutane-info.com/lawsuits.php

Attorney Michael Hook of the law firm Hook Bolton Mitchell Kirkland & McGhee in Pensacola, Florida, has put together a consortium of law firms to take on Hoffmann-La Roche in the courts. Hook has spent the last 20 years of his legal career mainly defending doctors, hospitals and insurance companies, but he described that his life changed dramatically in 2001 when he decided to take up the challenge of suing a major drug company because in his words one must commit "every waking moment and all of your resources to take them on."

Consortium of Firms Working on Accutane Litigation
http://www.law.com/jsp/law/sfb/lawArticleSFB.jsp?id=900005554550

Jury Validates Accutane Bowel Risk
http://goliath.ecnext.com/coms2/gi_0199-6746576/Jury-validates-Accutane-bowel-risk.html

In the article above, Hook said that Hoffmann-La Roche "knew what it was doing and made billions in profits but did nothing to assess its drug, did not do tests even though scads and scads

of people were reporting inflammatory bowel disease……..Some of my clients don't have intestines, don't have colons--it's horrible what they have to live with, it got to the point where I decided if I don't do this, who's going to? I knew it would require me to give up the rest of my practice and really work on it continuously. But how long has this been going on, and no one has gone after the company?"

Hook believes that the plaintiffs are on "solid ground with discovery evidence and experts." Dr. David B. Sachar is the plaintiffs lead expert. Sachar is the director emeritus of gastroenterology at Mount Sinai School of Medicine in New York and until last month served as chair of the FDA advisory committee on gastrointestinal drugs.

"Early on, [Sachar] said, 'I believe Accutane is causing inflammatory bowel disease,' His experts have reviewed discovery materials and testified that the manufacturer withheld documents about IBD and other key plaintiff issues."

The first four trials have already been decided in favor of the plaintiffs, and Roche has been ordered to pay Andrew McCarrell, Adam Mason, Kamie Kendall, and Jordan Speisman millions of dollars because Accutane caused their inflammatory bowel disease leading to surgical removal of their colons.

A short video from the Levin-Papantonio law firm in Pensacola, Florida
Accutane's history and its connection with severe gastrointestinal disorders
http://video.google.com/videoplay?docid=-8081722726487714383&hl=en

Accutane Documentary on Youtube: The Ghost Under My Pillow
http://www.youtube.com/watch?v=RGzK448fKyw

Accutane litigation websites
http://accutane.poweradvocates.com/accutane_side_effects.html
http://www.accutane-injuries.com/side_effects.html
http://www.levinlaw.com/PracticeAreas/accutane.asp
http://www.ennislaw.com/accutane.html
http://www.lawyersandsettlements.com/case/accutane.html?ref=article290

Los Angeles Times: Acne drug is target of new suits
http://articles.latimes.com/2007/apr/16/business/fi-accutane16

"Tim Robbins is like millions of Americans, most of them teenagers and young adults, who have taken the powerful drug Accutane and watched their embarrassing acne disappear within weeks. Robbins is also one of nearly 500 individuals who say they paid a terrible price as a result and are suing drug maker Hoffmann-La Roche Inc. The first trial opens today in Illinois. At issue is whether the company downplayed the risk that the medication could cause serious gastrointestinal diseases. But pharmaceutical giant Roche, which is based in Nutley, N.J., flatly denies it and maintains that there is no reliable evidence that Accutane causes inflammatory bowel disease. Many of the plaintiffs who contend that the treatment led to their conditions — ulcerative colitis or Crohn's disease — say they can be treated with drugs or suffer only

occasional but debilitating flare- ups. The conditions are characterized by abdominal pain, diarrhea and weight loss. The problem was much more severe for Robbins, 28, a former construction worker in Oak Ridge, Tenn. He had his colon removed and permanently lives with a colostomy bag. 'There are days when I wonder, why did this have to happen to me?' he said. Robbins' trial is expected to start this summer."

"Mike Papantonio, senior counsel at Levin, Papantonio, Thomas, Mitchell, Echsner & Proctor of Pensacola, Fla., one of five law firms representing the Accutane plaintiffs. Papantonio said lawyers would present documents in court that showed that the company long ago knew not only that the drugs could cause gastrointestinal diseases but also that they were more common than any other side effects listed on the drug's label. In addition, he said, there are more than half a dozen instances in which internal company documents show that the company describes the drug as a possible cause of the disease."

Accutane Maker Roche AG Ordered to Pay $2.62 Million to Patient Who Developed Inflammatory Bowel Syndrome After Using Drug
http://www.yourlawyer.com/articles/read/12872

Accutane Drugmaker Roche to Pay $2.5M for Man's Sickness
http://www.foxnews.com/story/0,2933,276175,00.html

Postponed Accutane trial set for Oct. 15 in Madison County
http://www.madisonrecord.com/news/197087-postponed-accutane-trial-set-for-oct.-15-in-madison-county

Florida man gets $7 million in lawsuit against Accutane
http://www.iht.com/articles/ap/2007/10/12/business/NA-FIN-US-Accutane-Lawsuit.php

Roche Owes $2.62 Million for Man's Illness, Jury Says (Update4)
http://www.bloomberg.com/apps/news?pid=20601085&sid=ahzh9Bep4qcs&refer=europe

Roche Must Pay Accutane User $7 Million for Illness (Update2)
http://www.bloomberg.com/apps/news?pid=20601202&sid=amiIZKeblTlE&refer=healthcare

Accutane Victim Awarded $7 million in Florida Lawsuit
http://www.newsinferno.com/archives/1909

Roche Must Pay $7 Million In Accutane Trial
http://www.pharmalot.com/2007/10/roche-must-pay-7m-in-accutane-trial/

Appeals Court Upholds $7 Million Accutane Judgement against Roche Pharmaceuticals
http://www.lawyersandsettlements.com/articles/10014/accutane-crohns.html

Accutane Injury Results in $10.5 Million Judgment
http://www.yourlawyer.com/articles/read/14268

Jury Award 10.5 Million to Accutane Victim
http://blog.ennislaw.com/2008/04/23/accutane-case-won-105-million-verdict.aspx

Accutane: Slipping Through the Cracks Everywhere
http://www.lawyersandsettlements.com/features/accutane-cracks.html

Accutane: "It was the darkest place I've ever been."
http://www.lawyersandsettlements.com/articles/01907/accutane-acne.html

Former Luvabull Takes On Drugmaker
http://www.nbc5.com/health/15218077/detail.html

Congressman Turns up the Heat on the FDA Over Accutane and Others
http://www.lawyersandsettlements.com/features/accutane-suicide.html

FDA Needs To Ban Accutane
http://www.lawyersandsettlements.com/articles/00334/Accutane_Ban.html

Roche puts Accutane profits over Lives of Consumers
http://www.lawyersandsettlements.com/articles/00299/Accutane_Profits.html

Accutane - Another Case of Too Little Too Late
http://www.lawyersandsettlements.com/articles/00163/accutane.html

Lethal Accutane still a Top Seller for Hoffmann-La Roche
http://www.lawyersandsettlements.com/articles/00290/accutane_sideeffects.html
http://www.opednews.com/articles/genera_evelyn_p_060828_lethal_accutane_stil.htm

Attorney Peter Kaufman on Accutane Litigation
http://www.lawyersandsettlements.com/articles/10501/-pharma-accutane-litigation.html

Accutane: Alleging high risks for heart and liver problems
http://www.lawyersandsettlements.com/search.html?keywords=Accutane

USA Today: Grieving father spends $1 million nest egg to investigate Accutane
http://www.usatoday.com/money/industries/health/drugs/2005-01-26-accutane-usat_x.htm

USA Today: Drugmaker rebuffed call to monitor users
http://www.usatoday.com/money/industries/health/drugs/2004-12-06-accutane-cover_x.htm

Accutane: Depression, Suicide and Degenerative Diseases
http://www.lawyersandsettlements.com/articles/01918/accutane-depression-lawsuit.html

Clear Skin with Killer Side Effects
http://members.tripod.com/~dhscribbler/acutane.pdf

"The lawyers and staff of Ennis & Ennis P.A. would like to congratulate attorney Mike Hook and his staff for their tremendous verdict in the amount of $10.5 million for a 24 year old Utah woman who was diagnosed with ulcerative colitis after taking Accutane. This has been a well kept dirty secret by the manufacturer Hoffmann-La Roche for many years. We are glad to see these cases come to light and hopefully the word will spread to teenagers and young adults who are still on the drug or are thinking of taking the drug. We have been working with Mike and his staff since 2003 on these cases and it has been a long hard fight. The manufacturer has stonewalled the litigants time and again and it is good to see these cases finally get to trial and let the truth come out. Mike and his team have won 3 straight trials in New Jersey state court in the amount of $2.5 million, $7.5 million and yesterdays verdict of $10.5 million. We are convinced, based on our research, that there are many more victims out there who have not correlated their illness to the drug accutane. Accutane has received much publicity for side effects including depression, suicide and birth defects. The real dark secrets lie in the correlation between accutane and IBD (Inflammatory Bowel Disease), Ulcerative Colitis, Crohn's, Liver and Kidney damage."

"(OPENPRESS) May 31st, 2007 -- Ennis & Ennis P.A. announced that it has been retained by almost 100 clients who have been diagnosed and treated for Inflammatory Bowel Disease (IBD), Crohns Disease, Ulcerative Colitis, Kidney and Liver Transplants. Today's $2,600,000 verdict against Hoffmann-La Roche validates our client's claims nationwide and in Canada. 'We have been working with trial team lawyer Michael Hook since 2003 on Accutane cases and we would like to congratulate Michael Hook, David Buchanan and all the dedicated professionals who did the behind the scenes work' said Attorney David F. Ennis. Attorney David Ennis is quoted as saying 'It is a great day in America when a citizen of Alabama can hire a lawyer in Florida and bring a claim in the great state of New Jersey against a Swiss manufacturer, (Hoffmann-La Roche one of the biggest and most profitable pharmaceutical companies in the world) and a jury of their peers over a three week time period can come to a reasonable verdict on liability and damages.' It renews your faith in the jury system and you hope American citizens realize that if they ever give up their right of trial by jury they will lose all power and leverage against major Corporations."

New Jersey Jury Awards $12.9 Million to Three Patients Whose Use of Roche Acne Medication Accutane Found to Cause Severe Bowel Illness
http://www.istockanalyst.com/article/viewiStockNews/articleid/2817847
http://www.lawyersandsettlements.com/settlements/12867/accutane-settlement-teens-awarded-12-9-million-in.html

"The three plaintiffs are all Florida residents - Kelly Mace, 25, of Pensacola, along with Jordan Speisman, 27, of Gainesville, and Lance Sager, 28, of Ft. Lauderdale. All were first prescribed Accutane nearly a decade ago while still in their teens to relieve adolescent acne. All three succumbed to various forms of IBD, including ulcerative colitis and Crohn's disease, while taking Accutane or shortly thereafter."

"Roche first advised physicians about a possible association between Accutane and inflammatory bowel disease in 1984. In the ensuing years, the evidence accumulated by Roche and outside scientists demonstrated that, far from a coincidence, Accutane was in fact inducing inflammatory bowel disease in Accutane patients. Nonetheless, Roche failed to strengthen its

warnings either to patients or prescribing physicians. The jury saw evidence of Roche studies, never published for the scientific and medical community, that Accutane's by-products damage the gastrointestinal tract and lead to degeneration and erosion of the intestinal lining -- a trigger for IBD. Significantly, those studies, which were performed in animal models specifically to test the gastrointestinal safety of the drug, tested exposures that were lower than those seen in patients taking Accutane. Also in Roche's files but not shared with the medical community, were hundreds of patient reports of IBD in connection with Accutane use. Notably, in numerous of the reports, the symptoms of IBD appeared with Accutane use, subsided when Accutane use was terminated, but then recurred following re-introduction of the drug. Roche repeatedly determined internally that Accutane was the best and only explanation for these IBD reports."

"This is an important outcome and consistent with the recognition by the medical community that Accutane is a trigger for IBD," said David Buchanan, a partner with Seeger Weiss in New York who served as co-counsel to the plaintiffs at trial.

"We applaud the jury's diligence and hope their verdict will finally break down the arrogance and stonewalling by Roche in denying Accutane's role in the prolonged illness of so many patients who took the drug unaware of the extreme, prolonged effects it would have on their intestinal tract," he added. He noted that Roche faces as many as 600 Accutane cases around the country.

Michael Hook served as lead counsel in the case. He stated, "It is unconscionable that faced with so much scientific proof that Roche has continued to deny its culpability in these cases. Since first acknowledging in 1984 that Accutane may be associated with IBD, the company has collected a mountain of evidence showing that Accutane in fact induces, causes, and aggravates IBD. Yet, Roche never shared that information with prescribing doctors or patients. Shockingly, Roche had internally contraindicated Accutane for IBD, another fact not shared with the medical community. As a result, the labeled warnings on IBD haven't changed to reflect the likely link, which most certainly would have caused most doctors to rethink prescribing Accutane and led patients to reconsider their potential for acquiring this horrific and debilitating disease."

Very few people know this but Accutane is not technically an acne medication, it was originally developed to be a chemotherapy drug back in the 1970's and is still used as chemotherapy today for leukemia, pancreatic cancer, brain tumors, and other types of cancers. It has powerful systemic cell division reducing effects throughout the entire body, and acne reducing skin dryness happens to be one of its side effects. Cancer chemotherapy drugs by their very nature are some of the most powerful and toxic pharmaceuticals used in conventional medicine. During clinical trials in the late 1970's, researchers discovered that some of their cancer patients had their acne cleared up during their chemotherapy. This was when drug regulatory authorities all around the world tossed their logic and common sense out the window and Accutane slowly became known as a popular treatment for acne. Roche accomplished this by paying off several different doctors (Dr. William Cunliffe, Dr. Douglas Jacobs, Dr. Susan Jick) to promote Accutane as a safe and effective drug for acne. United States attorney Mike Papantonio has fought and won in some of the most significant litigations against the pharmaceutical industry for product liability. Today he is working on Accutane. During a television documentary broadcast in Switzerland last year created by investigative journalist Serena Tinari, Papantonio said,

"The interesting thing about this drug it's that it was never intended for something like clearing up pimples. This was a drug that was intended for chemotherapy. Roche could not make enough money with it just with chemotherapy, so they said: Let's expand it. Let's sell it to more people. And they ended up selling it to people with acne."

"If you, today, were to ask Roche: Explain to me what is the mechanism, the bio mechanism of this drug. You know what? They wouldn't be able to tell you. They don't know. This drug has been on the market since 1982 and they have not spent one dime, not one single dime, trying to figure out how it works, how it goes about causing these side effects."

"You have 152, about 152 side effects. People would never make the choice to use this drug. Never. Once they understand how dangerous it is, there's no logic, there's no reasoning person that would say: I'm going to take Accutane to clear up pimples."

Congressman Bart Stupak was interviewed at the beginning, he said,

"My son went on Accutane in December 1999 and on May 14th, about 5 and a half months later he shot himself while on Accutane. This was completely out of characteristic of my son. He was a young man who loved life. He'd light up this room if he walked in right now. So after some time my wife just thought that maybe there could be some relation between Accutane and his suicide. I found that hard to believe: why would an acne medicine lead to disturbed thoughts or depression. We found that the FDA, the Food and Drug Administration here, in the United States, filed a warning in 1998. We had no knowledge of that. My first question was: why don't people know about this? Secondly, why would the FDA in 1998 put a warning note, but not tell people? And what led to the warning. Why the warning?"

Later in the program, Dr. Douglas Bremner, Professor of Psychiatry and Director of the Emory University Medical School Clinical Neuroscience Research, explained his research he'd conducted with Accutane and brain scans,

"We looked at a group of 13 individuals who were treated with isotretinoin, which is Accutane in the United States, and compared it to 15 individuals who were treated with antibiotics. And we looked at brain function before and after treatment, with antibiotic or isotretinoin. And we found a 21 % decrease in brain function over the frontal cortex, which is the brain region involved in emotion and mood, in the patients treated with isotretinoin, but not in the patients treated with antibiotic."

"I asked if they'd (Roche) be interested in providing medication or other support for the study and they weren't interested. Well, often times companies will give, provide free medication. I've done that all the time. They may not fund a study, but if you request, they'll provide free medication. So, I was surprised that they were not interested in providing even the medication. You can calculate that it takes 800 patients in order to have an adequate trial. And, you know, I've asked the FDA if they would request Roche to just provide the medication for a trial like that. And they told me that they don't have the power to do that. I mean, if they don't have the power to do that, then who does!"

"The effect is through protein transcription, that would imply that the effects would take longer to come on, but also would take longer to go away. Because, once you've started affecting protein transcription, you're basically talking about changing the structure of the brain. It could take weeks to refer back to normal. It's possible that some individuals would just stay that way. There will continue to be cases of suicide and depression. You know, Roche may continue to argue that they're not related, that suicide is common or that there's other extenuating circumstances. However, the science won't stop. There's even a new study that came out, it increases oxidative stress and causes DNA damage. So, I don't think that…..I think that most people would think twice about taking a drug that causes DNA damage. I mean, I certainly would."

The Ghost Under My Pillow
http://www.accutaneaction.com/swiss_tv/061114swisstv.html
http://www.youtube.com/watch?v=RGzK448fKyw

Roche orchestrated an elaborate smear campaign in their attempt to discredit Dr. Douglas Bremner and his research work. Click the following link to read the full story on Dr. Bremner's blog.

"Well I thank Hoffmann-La Roche Pharmaceuticals and my dispute with them about whether their acne drug Accutane can cause depression for: 1) deposing me 16 times; 2) calling me a liar); 3) attacking my professional reputation; 4) suing my university; 5) trying to get me fired from my university; 6) trying to get my paper on the effects of Accutane on the brain retracted; 7) accusing me of fraud to the Editor (yes, Robert Freedman MD) of the journal where the paper was published, which led to, more inquiries at my university."

"What is really sad about this whole sordid tale is how degenerated the so-called dermatology literature has become on the topic. For example, the most commonly cited study to support the statement that acne is associated with depression, a study that has been cited several hundred times by dermatologists writing in the literature, involved only ten patients with acne and no comparison subjects (Gupta et al., 1990). No statistics were performed (obviously since there was no comparison group). Scores on the questionnaires for anxiety and depression were not related to severity of acne."

"And the fact is that the rest of the literature isn't any better. Objective measures of acne do not correlate with severity of anxiety or depression. Acne does not cause major depression. It is simple as that."

"Sure, kids worry about their zits and feel better when they go away, but the studies do not support the conclusion that acne causes major depression, and that treatment of acne cures depression."

Are Dermatologists Dips**ts? The Depressing Accutane Tale
http://www.beforeyoutakethatpill.com/index.php/tag/accutane/

Can You Please Put Some Sugar on This Crap?

http://www.huffingtonpost.com/doug-bremner/can-you-please-put-some-s_b_125072.html

Here's a question for all the dermatologists and everyone else that doesn't believe Accutane affects brain function, and therefore had nothing to do with all of the reported psychiatric injuries, suicides, and murders. If Accutane supposedly only affects the skin, then why do oncologists use it for pancreatic cancer, leukemia, brain tumors and other certain types of cancers? To corroborate, here's a quote from a website devoted to pancreatic cancer therapies.

http://www.seniorfitness.com/Show_Disease_and_Healing_Protocol.html?ProtID=113&Title=Pancreatic%20Cancer

"Accutane: Based on the need to inhibit pancreatic cancer cell division at different stages of its growth and induce apoptosis (programmed cell death) of cancer cells, multiple therapeutic modalities are often recommended. One successful treatment modality is to combine the differentiating-inducing drug Accutane (13-cis-retinoic acid) with other chemotherapy drugs, such as 5-FU. Both Accutane and 5-FU are toxic drugs that must be carefully administered by a medical oncologist. A combination of 13-cis-retinoic acid (Accutane) and interferon-alpha was tested in a Phase II trial of 22 patients with pancreatic cancer. One patient experienced partial remission and 14 patients demonstrated stable disease for about 5 months (Brembeck et al. 1998)."

'Chemo brain' real for many cancer patients: study
http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20080421/chemo_brain_080421?s_name=&no_ads

"The research concludes that a common chemotherapy drug, known as 5-fluorouracil (5-FU), causes stem cells in the central nervous system to die off well after treatment has ended. The resulting side effects are often referred to as "chemo brain."

"Because of our growing knowledge of stem cells and their biology, we can now begin to understand and define the molecular mechanisms behind the cognitive difficulties that linger and worsen in a significant number of cancer patients,"

"The 5-FU chemotherapy drug treats cancer by halting cell division, and has been used for more than 40 years. It is often given in combination with other chemotherapy drugs, and is commonly used to treat breast, ovarian, stomach, colon, pancreatic and other types of cancer."

Joseph Mercola, D.O. states on his website "Chemotherapy, which has been one of the principal treatment methods for the past 50 years, works by killing all cells - throughout your body - that multiply and divide rapidly. This would include cancer cells, but also other rapidly multiplying and dividing cells, such as: Bone marrow (which produces blood), Digestive system, Reproductive system, Hair follicles." http://www.mercola.com/

Since Accutane is fat (lipid) soluble, it is one of the few drugs that is able to cross the blood-brain barrier and get into the central nervous system. This fact alone explains how it can elicit devastating psychiatric side effects, and why it is often used as chemotherapy for brain tumors.

Accutane has been on the market for the past 25 years and during that entire time Hoffmann-La Roche has specifically declared in the Physician's Desk Reference that its exact mechanism of action is unknown. In my opinion, this has basically been their way of sidestepping issues regarding all the many harmful side effects Accutane causes to the human body, and also to distract people from gaining insight about how this drug does what it does. They neglect to mention that Accutane is a systemic chemotherapy agent that reduces cellular proliferation of the sebaceous glands in the skin all over the body (which is why it's so effective against acne), and also does the same thing to the cells lining the digestive tract, areas of the brain, eyes, and mucous membranes (causing a lot of dryness). To corroborate my previous statement, take a look at what scientist James Crandall says in this scientific study which can be found on PubMed. He is stating point blank this is how Accutane works and this is what's causing the side effects.

"Retinoic acid (active form of Accutane) induces differentiation and reduces proliferation of stem and progenitor cells. It works on acne by inducing similar events in basal sebocytes. These same actions also lead to 13-cis-retinoic's (Accutane's) side effects, and these are directed towards proliferating cells in the adult such as in the skin, gut and bone."

"A wide ranging effect of retinoic acid is to inhibit proliferation in dividing cells, and this accounts for its frequent consideration as an anti-cancer agent."

This study was published in 2004, here is its abstract.

"The active component of the acne drug Accutane is 13-*cis*-retinoic acid (RA), and it is highly teratogenic for the developing central nervous system. Very little is known, however, regarding the effect of this drug on the adult brain. Regions of the brain that may be susceptible to RA are those that continue to generate new neurons. In the adult mouse, neurogenesis is maintained in the hippocampus and subventricular zone. This report demonstrates that a clinical dose (1 mg/kg/day) of 13-*cis*-RA in mice significantly reduces cell proliferation in the hippocampus and the subventricular zone, suppresses hippocampal neurogenesis, and severely disrupts capacity to learn a spatial radial maze task. The results demonstrate that the regions of the adult brain where cell proliferation is ongoing are highly sensitive to disruption by a clinical dose of 13-*cis*-RA."

http://www.pnas.org/content/101/14/5111.full
http://www.pnas.org/cgi/content/abstract/101/14/5111

In the quotes above, Crandall hints at Accutane's mechanism of action but he doesn't specifically say the actual mechanism because he doesn't know about the telomere (pronounced TEE-LA-MEER) research that I have discovered. Recently I have discovered research showing that all-trans retinoic acid (abbreviated ATRA which is the final biologically active metabolite that Accutane turns into) down-regulates the telomerase enzyme (pronounced TEE-LA-MER-AZE) and induces telomere shortening and cell death. This I believe is the mechanism of action. Accutane causes telomere shortening leading to permanently arrested cell division / proliferation.

So why are short telomeres a bad thing to have? Here's a quick rundown of telomere biology. Cells all over the body are replaced by means of cell division, and there is a limit on the number of times that they may successfully divide. This is known as the Hayflick Limit. Most cells in the body divide about 50 times before they stop dividing and die a natural death. The mechanism that controls this cell division lies within the telomere / telomerase, which is a cap like structure on the end of all the different twenty three pairs of chromosomes. Chromosomes are the helical structures of DNA that are found inside the nucleus of all cells in our body which carry our genetic code. The telomere chain and its length can be thought of as a string of beads (repeating code at the end of every DNA strand), with one bead falling off the string each time a cell divides. Therefore, the telomere shortens up a little bit every time a cell divides, and again this places a limit on the number of times a cell can replicate itself, known as the Hayflick Limit. Once these beads run out and disappear, the cell stops dividing and undergoes programmed cell death (AKA apoptosis). The constant process of telomeres getting shorter eventually leads to the death of the cell and over time this cumulative cell death leads to one of the major components of the aging process. However, there exists a specialized enzyme called telomerase which acts to repair damage to the telomere, maintain its stability, and extend the length of the telomere beads, thereby overcoming the Hayflick Limit. Germ line cells and cancerous cells continually express telomerase in such a way that they never run out of telomere beads and therefore remain immortal. Telomerase is naturally expressed more in cells in the body that are the most rapidly dividing: the immune system, skin, bone, digestive tract, mucous membranes, etc. because these cells undergo much more cell division (more turnover) throughout a person's lifetime and therefore need to have their string of beads repaired and relengthened more often. Right now I'm going to include a relevant quote from Dr. Aubrey De Grey's new book titled *Ending Aging*, which can be found at Amazon.com or any major bookstore. Dr. De Grey is a world famous Biogerontologist, which in a nutshell means he studies the underlying causes of the aging process.

"If it weren't for telomerase, this gradual shortening would eventually lead to the complete loss of the telomeres in cells that replicate frequently during the lifespan, and thus the gradual erosion of the genes themselves. Telomerase periodically relengthens the telomere before it becomes critically short." (De Grey, 294)

10% of cancer cells use an alternative process to continue their cell division known as alternative lengthening of telomeres, but 90 % of cancer cells activate the telomerase enzyme in such a way that it continually rebuilds the telomere chain so that these cells never run out of cell divisions and therefore become immortal. This is one of the major defining hallmark characteristics of cancer. Cells divide and grow out of control and don't die off like they are supposed to. The telomere Hayflick Limit can be thought of as a cellular countdown clock mechanism that is in place to specifically protect us from renegade cells growing wildly out of control (AKA cancer). The following quote from Dr. Aubrey De Grey's *Ending Aging* explains what would happen if cancerous cells were deprived of telomerase or alternative lengthening of telomeres.

"Either way, without a way to renew their telomeres, the single-minded multiplication of potential cancer cells rapidly grinds to a halt as it reaches the end of its telomere "rope," and we wind up with a tiny (and generally short-lived) lump in our bodies instead of a life-threatening, malignant condition." (De Grey, 295)

From what I've observed, I believe the people who suffer the chronic latent side effects of Accutane have the opposite problem that people with cancer have. With cancer patients, there's too much uncontrolled disorderly rapid cell division going on, but with Accutane patients, there's too little normal necessary bodily cell division or sometimes none at all because the Accutane has caused critical telomere shortening, inducing growth arrest and cell death in various areas of the body where cell proliferation is supposed to be ongoing.

What's bad about Accutane is that there's a huge amount of individual variability when it comes to the side effects. For some people, it takes multiple courses of Accutane to induce permanent side effects, but for others all it takes is one round to put their bodies past the point of no return. Different people get different combinations of side effects and they are very unpredictable, because through influencing DNA transcription (which is what all retinoid/vitamin A drugs do), it causes random groups of cells all over the body to differentiate and shut-down when they are not supposed to. This is why it is used in chemotherapy. Chemotherapy drugs kill rapidly dividing/proliferating cancerous cells, but they also kill the healthy rapidly dividing/proliferating native cells of the body along with the cancer. Accutane binds to the vitamin A (retinoid) nuclear receptors RAR and RXR on the surface of the nucleus inside every cell in the entire body and changes the way that the cells read their genes (protein transcription). This is why Accutane has an extremely long list of side effects involving every tissue and every organ in the human body. The cells that are the most vulnerable to this effect are the ones that need to divide and proliferate (undergo mitosis) more often.

The severity of Accutane long-term side effects all depends on how far the course of Accutane down-regulated the telomerase enzyme and shortened the telomere length. Here's another quote from Dr. De Grey's book where he explains what would happen if telomerase was completely down-regulated.

"Deleting telomere elongation capacity throughout the body would also be life-threatening, because it would mean that our regular, proliferating cells (like those in the skin or the lining of the gut) would suddenly have iron limits on their ability to reproduce themselves and thus replenish tissue. From the moment that we denuded our cells of telomerase, a clock would be ticking. With each division the telomere would shorten by a notch from whatever it had been when we took telomerase out. We would be under the specter of a rather horrible death, as our stem cells went offline one by one under replicative senescence (see Chapter 10): with each failure of a stem cell responsible for supplying key functions, the tissue would fail to be renewed and would slowly degenerate." (De Grey, 297)

Accutane and ATRA (all-trans retinoic acid or Vesanoid) are very similar drugs, they are both retinoids, they have very similar side effect profiles and pharmacokinetics and they are almost chemically identical. Interestingly, Roche states a 14% incidence of depression for 10 mg of Vesanoid, with the knowledge that this is exactly what 40 mg of Accutane interconverts into. Two of ATRA's side effects are dry eyes and dry skin, so it would work against acne, but Roche hasn't studied it against acne because they've been too busy making a killing (pardon the pun) selling Accutane. If you read over ATRA's side effect profile in the link I've put below, you'll notice how it's very similar to Accutane (they both cause retinoid toxicity AKA vitamin A

toxicity). To clarify, here are the brand names and chemical names for these two drugs that are both manufactured by Hoffmann-La Roche.

Accutane (used for Acne)
Isotretinoin
13-cis retinoic acid

Vesanoid (used for Leukemia)
Tretinoin
All-trans retinoic acid (ATRA) or retinoic acid

Accutane and Vesanoid information on Chemocare.com
http://www.chemocare.com/bio/accutane.asp
http://www.chemocare.com/bio/vesanoid.asp

Since a certain percentage of Accutane metabolizes into ATRA (about 30%), and since the ATRA metabolite is how Accutane exerts its pharmacological actions on the body, there's no doubt that if ATRA causes telomere shortening then Accutane also causes telomere shortening. If Accutane truly does cause telomere shortening and down regulation of the telomerase enzyme, this could mean huge significant implications for maintaining adequate cell proliferation all over the body for the rest of a former Accutane patient's lifetime. In other words, Accutane, being a potent chemotherapy drug, attacks and damages the cells in the body that are supposed to remain dividing and proliferating for a person's entire lifetime. If cells have shorter telomere lengths (shorter telomeres), they get closer to the Hayflick Limit and can't divide/proliferate as much or they go on to experience growth arrest and cell death (apoptosis). This is how Accutane reduces acne, and why in some cases, the acne doesn't come back, and the patient is left with permanent dry skin, dry mucous membranes, digestive problems, hair loss, and other various permanent side effects. During the course of treatment and after, Accutane has increased the cell division / turnover rate so drastically (new cells are born and die at a faster rate), that these cells run out of cell divisions and are driven into their Hayflick Limit. This can be illustrated by observing what happens when somebody eats polar bear liver (contains extremely toxic levels of vitamin A similar to Accutane) and their skin starts to peel off all over their body in thick giant sheets from the increased cellular turnover rate, also a potential side effect of Accutane. The cell division rate (beads falling off the string) has been increased so fast and telomerase has been down-regulated so much that it cannot repair the telomere chain (the beads on the string) before the cells lose all of their cell divisions (beads) and enter growth arrest (Hayflick limit). Here's an excellent definition of the Hayflick Limit.

"Dr. Leonard Hayflick discovered that mammalian cells divide only a fixed number of times. This "Hayflick Limit" was later proven to be caused by telomeres on the ends of chromosomes that shorten with each cell division. When the telomeres are gone, the DNA can no longer be copied, cell division ceases, and cells enter replicative senescence or old age."

Conduct some research online and through Wikipedia on cell division (mitosis), telomerase, telomere shortening, and the Hayflick Limit, and how they have long been considered to play a role as one of the major components of the aging process. Another observation that would be worthwhile to consider is that people with the premature aging disorder Progeria have shortened

telomeres. So there is enough evidence to predict a possible backlash that is going to occur when this information gets fully verified, that Hoffmann-La Roche and the American Academy of Dermatology have given a drug that causes a form of premature aging to millions of teenagers and young adults with acne. Specialized tests are available that can assess telomere shortening, validating the damage caused by Accutane. One of them is called the Terminal Restriction Fragment southern blot TTAGGG telomere length assay.

It's imperative to understand that stopping Accutane doesn't necessarily mean that the user is in the clear. There are several reports by people who claim that some of their side effects, particularly the worst kinds, didn't emerge until years after they stopped Accutane. This drug is proving to have a chronic latent effect on people's bodies, which is also how it permanently cures their acne, with lots of collateral damage of course. If people investigated further into their own use, there could very well be a massive backlash when this information gets out, even with people who took a low dosage and got good results from their course of Accutane and so far haven't developed any complications or chronic health problems. My impression, after conducting many hours of research, is that there are thousands of people out there with really bizarre and unusual chronic health problems as a result of their exposure to Accutane, but they just haven't investigated and made the connection yet.

I always knew that Accutane's mechanism of action would reveal itself by examining the way that retinoids are used in chemotherapy. When retinoids are used for chemotherapy, at least they make an attempt to tell patients how the stuff works and warn them about the side effects. This study below, published back in 2001, is the smoking gun for Accutane's mechanism of action, because ATRA (all-trans retinoic acid or Vesanoid) is the active metabolite that 13-cis retinoic acid (Accutane) turns into. Nobody besides me has made this connection yet. Nobody has posted any information about retinoids and how they cause telomere shortening on the Ro/Accutane Action Group forum. Here's a quote from the abstract of a study which can be found at the following link.

Retinoids down-regulate telomerase and telomere length in a pathway distinct from leukemia cell differentiation
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=34517

"A second pathway of hTERT regulation, identified in the RAR-responsive, maturation-resistant NB4-R1 cell line, results in a down-regulation of telomerase that develops slowly during two weeks of all-trans retinoic acid (ATRA) treatment. This pathway leads to telomere shortening, growth arrest, and cell death, all events that are overcome by ectopic expression of hTERT."

Here's another interesting quote from the scientific abstract of a more recent study published in 2006, I've provided the link to this study below.

Telomerase targeting by retinoids in cells from patients with myeloid leukemias of various subtypes, not only APL
http://www.nature.com/leu/journal/vaop/ncurrent/full/2404127a.html

"These results support the idea that, by hTERT targeting, retinoids can induce telomere

shortening and cell death and their integration in therapy protocols for myeloid leukemias refractory to maturation should be considered."

So to sum all of this up, these research studies I listed above show that long-term treatment with ATRA (all-trans retinoic acid), which is almost chemically identical to Accutane, causes "telomere shortening, growth arrest, and cell death." The cells that the researchers tested were cancerous cell lines, but if ATRA causes these effects in cancerous cell lines, then it is highly likely that it will do the same thing to our body's own rapidly dividing/proliferating cells such as the cells in the bone, skin, digestive tract, and even the hippocampus and subventricular zone in the brain.

Another significant observation which can be gleaned from this research is that if ATRA causes telomere shortening, and this is also the mechanism of action for how vitamin A toxicity causes many side effects and reduces cell division, then telomere shortening could explain why lots of people have reported that consuming high amounts of vitamin A or foods rich in vitamin A after their course of Accutane worsens their side effects, especially the problems related to dryness. In other words, it explains why for some people, the side effects become much worse after they stop Accutane, because the dietary vitamin A they need to stay alive might be slowly killing them because Accutane has shortened their telomeres too far. A search on the Internet reveals an abundance of information about vitamin A and retinoid compounds being inhibitors of telomerase.

Vitamin D3, Vitamin A and The Prevention of Tumor Cell Immortality
http://grouppekurosawa.com/blog/2006/01/vitamin-d3-vitamin-and-prevention-of.htm

"This subject is complicated so forgive me if my explanation is not completely understandable. Telomeres exist at the ends of chromosomes. As chromosomes replicate during cell division, the telomeres protect the chromosomes from damage and cell death. Yet telomere function declines as cells continue to divide, and the ends of chromosomes become progressively shorter. After a prescribed number of cell divisions, the cell dies. This is referred to as the limited lifespan of somatic cells. As cells grow, the ends of their chromosomes progressively shorten until they die...but NOT in cancer cells."

http://www.ncbi.nlm.nih.gov/entrez/queryd.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15520642&itool=pubmed_docsum

"A more technical discussion of this phenomenon can be found in the following paper. Click the Acta Pharma... box to read the paper online."

http://www.ncbi.nlm.nih.gov/entrez/queryd.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15842766&itool=pubmed_docsum

"Telomerase is the enzyme that corrects the shortening of the chromosomes as they continue to divide. This enzyme is not active in normal cells, but it is very active in at least 90% of all cancers and leukemias. This means that telomerase expressing cells can continue to divide over and over without fear of dying of old age. Cancer cells that possess active telomerase activity

can survive, while non-active varients will die. This is dogma and it is carved in stone. It doesn't make ANY difference if the cancer cells are activated by oncogenes, such as RAS, or if the cancer cells are of a particular genetic makeup, the chromosomes in these cells will shorten, causing the death of these cells, unless telomerase activity is activated."

"There is no shortage of biotech companies out there who would give anything if they could only develop telomerase inhibitors. They should stop trying. Vitamin D3 and vitamin A, combined, inhibit the SYNTHESIS of the catalytic unit of telomerase. This means that these two hormones will not allow cancer cells to divide indefinitely. And that ain't bad. The following study was conducted in prostate cancer cells, but the principle applies to ALL cells."

http://www.ncbi.nlm.nih.gov/entrez/queryd.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12939463&itool=pubmed_docsum

"ONLY the heterodimer of vitamin D3 and vitamin A receptors can inactivate the telomerase gene. So get these supplements integrated into your daily routine. Stay tuned..."

Learn Genetics: Are Telomeres The Key To Aging And Cancer?
http://learn.genetics.utah.edu/content/begin/traits/telomeres/index.html
http://learn.genetics.utah.edu/content/tech/cloning/cloningrisks/index.html

"Yet, each time a cell divides, the telomeres get shorter. When they get too short, the cell no longer can divide and becomes inactive or "senescent" or dies. This process is associated with aging, cancer and a higher risk of death. So telomeres also have been compared with a bomb fuse."

"Without telomeres, the main part of the chromosome - the part containing genes essential for life - would get shorter each time a cell divides. So telomeres allow cells to divide without losing genes. Cell division is needed so we can grow new skin, blood, bone and other cells when needed."

"An enzyme named telomerase adds bases to the ends of telomeres. In young cells, telomerase keeps telomeres from wearing down too much. But as cells divide repeatedly, there is not enough telomerase, so the telomeres grow shorter and the cells age."

"Geneticist Richard Cawthon and colleagues at the University of Utah found shorter telomeres are associated with shorter lives. Among people older than 60, those with shorter telomeres were three times more likely to die from heart disease and eight times more likely to die from infectious disease."

Vitamin A Cancer Adjuvant Therapy from the Life Extension Foundation
http://www.lef.org/protocols/prtcl-027h.shtml

"Vitamin A offers protection against radiation induced tissue damage, down-regulates telomerase activity, and is involved at almost every juncture of cancer control."

Telomere.net
http://www.telomere.net/

Vitamin A and Health
http://grouppekurosawa.com/blog/2006/01/vitamin-and-health.htm

Vitamin A
http://www.sahealthinfo.org/nutrition/vitaminminerals/vitamins/vitamin_a.htm

In my opinion Roche stating that "the exact mechanism of action is unknown" for the past 25 years is just a ruse to distract people from learning the information that the systemic cell division reducing effect of retinoic acid is specifically what's responsible for making their acne go away and causing many of the side effects. James Crandall's statement "A wide ranging effect of retinoic acid is to inhibit proliferation in dividing cells, and this accounts for its frequent consideration as an anti-cancer agent" is good enough for me as an explanation for the mechanism of action. But I've gone one step further and identified the mechanism. Being a systemic chemotherapy agent, Accutane does not know the difference between cancer and your body's own rapidly dividing cells. With the knowledge that many parts of the human body, such as the skin, nasal passage, immune system, areas of the brain, digestive tract, bones, lungs, mucous membranes, bladder, urinary tract, sexual organs etc. rely on rapid cell division/proliferation to sustain their proper function throughout a person's lifetime, this information about retinoic acid having a "chemotherapy like" cell division reducing effect becomes extremely important. Because it means that if you take too much Accutane for too long of a period of time, you are essentially slowing down or stopping cell division in areas of your body where cells are supposed to remain dividing for your entire lifetime. In my opinion this is what's causing most of the chronic long-term side effects, these people basically have the opposite problem that people with cancer have. As I've discussed in depth, the explanation for the mechanism of action likely involves human telomerase reverse transcriptase (hTERT), the chief regulator of cell division in our rapidly dividing cells. It has already been shown that retinoic acid down-regulates hTERT in cancerous cells, which is more than enough evidence to call for an investigation of its effects on hTERT in the human leukocytes, enterocytes, keratinocytes, sebocytes, endothelial progenitor cells and other various progenitor cells. Specific tissue biopsies and blood tests before and after a course Accutane will identify the extent to which cell division has been reduced.

As a result of Accutane, cells in many different areas of the body have a decreased ability to divide and proliferate, which is why the mucous membranes, the nasal passage, eyes, lips become very dry, and this also happens to various areas of the digestive tract, decreasing the integrity of the mucosal barrier that protects the gut wall, which is then more vulnerable to sustaining damage and developing into inflammatory bowel disease. The digestive tract can be thought of as a tube (your body is hollow) that is technically outside of the body because the mucosal layer is what protects us from pathogens and the harsh substances of digestive metabolism. Just like the skin, the lining of the digestive tract is a fortress that separates our bodies from the outside world. This protective barrier becomes dysfunctional and gets diminished after Accutane because the cells can't divide as much. One reported side effect is cracking and severe dryness of the region around the anus, leading to rectal bleeding. This isn't

surprising because a very common side effect is severe cracking and dryness of the lips (exfoliative cheilitis), which is another mucous membrane.

For all the people out there who like to use topical retinoids like Retin-A on their skin, be careful not to use it too often (not more than once per week) or else you might induce too many cell divisions (peeling skin) which could lead to the cells hitting their Hayflick Limit (skin cells can't turn themselves over anymore). Many misinformed people have been lead to believe that the Hayflick Limit is an urban myth when it comes to topical retinoids and agents used for facial exfoliation. Well, listen up because I've got the straight dope right here. Topical Retin-A works by burning off a layer of skin to try to create a better one. It is tretinoin, a retinoid also known as all-trans retinoic acid or ATRA, and one of the scientific studies I've referenced and discussed in-depth above shows that long-term treatment with ATRA targets human telomerase reverse transcriptase and induces telomere shortening, growth arrest and cell death (Hayflick Limit). Therefore, in light of this new information, what do you think could happen if you undergo too many facial exfoliations or apply topical Retin-A on your face too often?

Does anyone remember the drug Thalidomide, an anti-nausea medication prescribed to pregnant women in Europe back in the late 1950's and early 1960's? This drug caused approximately 10,000 babies to be born with severe debilitating or deadly birth defects. The scope of the Thalidomide tragedy was so awful and incomprehensible that governments around the world, including the United States, proclaimed that they needed to learn a lesson from this tragedy and that such a catastrophe must never be allowed to happen again. Well, guess what, it has happened again, just in a more out of the spotlight, clandestine manner. Accutane is Thalidomide Jr. and the devastation caused by Thalidomide is dwarfed by the devastation caused by Accutane. It has been estimated that in upwards of 50,000 infants have been exposed to the horrific teratogenic (birth defect causing) effects of Accutane during the quarter of a century that it has been on the market. The only reason Accutane is still on the market today is because of abortion, because without abortion, it would've been impossible to cover everything up for so long. In the past, if you were a woman on Accutane and you became pregnant, the dermatologists would recommend that you get an abortion. But hold on just one minute. Should having to get an abortion be allowed because of a side effect of taking an acne medication? By not giving out Accutane to so many people in the first place, this problem would be solved. Abortion and patient confidentiality are the methods used by Hoffmann-La Roche and the American Academy of Dermatology to suppress the shocking evidence about the real number of infants severely affected by Accutane. Investigative health journalist Bill Sardi sums up this situation by saying,

"Pimpled people have been poisoned with a vitamin/drug. Unlike Thalidomide, a drug that medical doctors were unaware caused birth defects, it was well known that Accutane, a synthetic form of vitamin A, caused malformed babies before it was placed on the market. Elisabeth Robert, MD, PhD, at the European Institute of Genomutations in France, says Accutane is not well-known for its link to birth defects whereas Thalidomide is. So one drug, Thalidomide, has been removed from the marketplace, while a similar drug, Accutane, experiences robust sales" (Accutane: A modern horror story, www.knowledgeofhealth.com)

In 1990, an internal FDA memo by Dr. David Graham (the same FDA drug safety scientist who

later blew the whistle on Vioxx in 2004) said that Accutane was an "imminent hazard" to public health and needed to be taken off the market immediately. Graham stated in the memo,

"As our data on drug use and contraceptive failure show, there probably have been between 15,000 and 18,000 pregnancy exposures to Accutane since its appearance on the market in 1982. The magnitude to fetal injury and death has been great and permanent, with 11,000 to 13,000 Accutane-related abortions, and 900 to 1,100 Accutane related birth defects…….Accutane poses an imminent hazard to public health, and as such should be withdrawn immediately from the market."

More recently it was revealed that,

"An FDA official at the February 2004 advisory committee acknowledged that there are probably 3,500 Accutane exposed babies each year in the United States, most are aborted! Hoffmann-La Roche claims that they do not have to report the abortions because, to use their words, a fetus is not a human being and it does not have to be reported under the FDA reporting system."

Human Teratology: Isotretinoin and Vitamin A
Presentation by Dr. Edward Lammer MD
http://www.youtube.com/watch?v=ACUZZzW3I4w

The New York Times: Biologists Identify 'Impresario' of Life In Vitamin A
http://www.nytimes.com/1990/03/20/science/biologists-identify-impresario-of-life-in-vitamin-a.html?pagewanted=all

The recently implemented IPLEDGE program (designed to eliminate Accutane pregnancies) has turned out to be a failure because despite its implementation many women have still became pregnant while on Accutane, and those are only the cases that have been reported. Congressman Bart Stupak says there have been instances of people getting pregnant, hushing it up with their dermatologist, getting an abortion, and not reporting it to anybody. In his recent statement to the FDA Advisory Committee Hearing on iPLEDGE, held on August 1st, 2007, Stupak also talks about how the FDA defeated the proposal for a mandatory registry of birth defects and psychiatric side effects,

"It is difficult to understand how the FDA can knowingly allow hundreds of birth defects to occur per year and remain silent. The FDA's attempt to say nothing about Accutane birth defects is summed up in this email, 'As for the 'needle, I think you and a lot of other non-dermatologists are in for a major shock IF the truth is ever exposed. I know that I am going to say is anecdote, but I personally know several derms whose patients have become pregnant on Accutane and NOT A SINGLE one reported it (except to their lawyer). And I don't even know that many derms, as I am not into the local derm scene!! […….] Roche and the AAD [American Academy of Dermatologists] are so adamantly opposed to collecting the real number of exposed fetuses for a reason and I personally do not believe them when they say it is concern for patients' privacy (we do NOT have to compromise that in any way to collect the data). I think it is a concern about the public outcry/outrage that will ensue if the truth comes out.'"

"As we know, the FDA dropped the mandatory patient registry and certification of practitioners whose prescribe Accutane to prevent birth defects and psychiatric injuries. Once again, the FDA succumbed to Roche's pressure and the registry and certification was abandoned. Each time the Advisory Committee made recommendations to limit the distribution and use of Accutane, Roche pressured the FDA to protect and increase its sales of Accutane. In fact, the latest defeat of the mandatory registry and certification will benefit Roche by approximately $450 million. After all the devastation this drug has caused teens!!!! What special powers or charm does Roche have with the FDA? Many are starting to ask that question." It is time for this committee on behalf of the American people to "start asking that question" what is the special power or charm that has allowed Roche to market Accutane which has caused death and devastation among our young people?"

http://www.house.gov/stupak/accutane_ipledge_080107.shtml

Warning! Don't skip over this next section.

For some people Accutane has caused them permanent severe sexual side effects like painful intercourse in men and women, erectile dysfunction, genital hypersensitivity, urinary discomfort/pain (interstitial cystitis), and severe dryness of the vaginal lining and penis. These side effects are most likely due to Accutane causing excessive thinning of the skin on their genitalia, with even the possibility of it sloughing off the entire top layer of skin, and degrading / drying out the mucosal barrier lining the bladder and urethra. Other cases exist where people can't kiss anymore because Accutane induced a severe lip condition called exfoliative cheilitis, which causes their lips to feel extreme hypersensitive pain if anything touches them. To this day these side effects are not included among Accutane's incredibly long list of warnings in its package insert. There's an M.D. on the Internet named Dr. Kevin Pezzi who discusses Roche's cover-up of Accutane's permanent sexual side effects in his book titled *The Science of Sex* and here at his website www.erbook.net/accutane initially posting this information 6 years ago.

The Sexual Effects of Accutane
http://www.erbook.net/accutane
http://www.sexualtips.net/accutane_affecting_sex.htm

Many stories can be found on the Internet written by individuals with various sexual side effects from Accutane. Here's an example from the Ro/Accutane Action Group Forum.

"This is beyond personal, but I am at my wit's end, and I'm desperate for any solutions out there. This post is regarding a mature subject matter, and it's not pretty, so read on at your own risk.

I finished a course of accutane about 6 months ago. Since that time, the skin on my penis has progressively deteriorated. Strange pinkish/reddish patches have cropped up on the glans. The glans has become permanently red in some places and dark brown in others and has become very rough and irritated. Some of the skin surrounding the meatus has peeled away and refuses to heal. One side of my urethra has become red and occasionally will tear, bleed slightly, and then scab over. The skin on the entire shaft has become so incredibly thin that all the veins are visible and painful to the touch. The entire area is incredibly sore, and brushing up against anything

(including clothing) is unbearable.

No doctor can figure out the problem. I have been tested for every STD on the books (herpes, HIV, syphilis, gonorrhea, chlamydia), and they have all come back clean. I've been given prescription oral antifungal medicine and used topicals, but they were useless. I've also been given medium strength steroids and protopic from one doctor who believed it could be psoriasis - but no luck in fixing the problem.

At this point, I'm pretty much certain accutane caused my condition. My symptoms do not match up with any skin/genital disease on the books, and the temporal proximity in taking the medicine and the onset of symptoms, while possibly coincidence, is more likely indicative of an adverse reaction to the medicine. The reason I am posting is not to wage a war against Roche (though I certainly respect that others want compensation for their pain). My purpose is to see if anyone else out there has had this problem as a result of taking accutane, and if so, whether they have found any way to make it go away, or at the very least, more bearable.

Has anyone found that their problems have improved with time?

I am really struggling here. I used to have such a nice life, and I would do anything in the world to have it back. Any help is much appreciated.

Thanks."

Comment from a Medical Doctor

"I have used Accutane myself years ago, and I have regretted doing so ever since. A few weeks after I began using it, my libido decreased dramatically. Even worse, my ability to experience sexual pleasure was greatly diminished as well. While I can feel some pleasure, it's much less than before. Quantitating such a subjective thing is obviously difficult, but I'd estimate that it is 90 percent less than what it once was. Even though I am a physician, I have discussed this problem with other doctors (urologists, a neurologist, and internists) and no one had any idea what to do about this problem. I've researched it myself, and I don't know what--if anything--can be done to reverse it. The manufacturer claimed to have never heard of this reaction before, but they could simply be saying that to avoid legal consequences. I HAVE heard others say they've had similar problems after using Accutane, and I think that many people may have had the problem yet never felt comfortable discussing it with anyone. (Consequently, the true incidence may be far greater than what anyone suspects.) In my case, it took years before I had the courage to mention this to anyone except my girlfriend -- it's not an easy thing to discuss. While Accutane achieves a long-term control of acne in SOME people, I think its potential complications outweigh its utility in that regard. There are numerous other drawbacks to this drug in addition to the one that I discussed above, so I'm not kidding when I say that I'd rather play Russian roulette than to take Accutane."

These side effects have been acknowledged in other countries (In a 1994 study, the UK's Dr. William Cunliffe wrote about Accutane causing severe dryness of the penis, using the medical term Balanitis) and they've been reported to the FDA and other regulating bodies for the past 20

years (read through the list of ADRs on Congressman Bart Stupak's website). But the Feds and Roche (remember the pharmaceutical companies basically own the FDA) have done nothing to warn patients because this is the one side effect that would tend to strongly dissuade people from taking Accutane for their acne, plus Roche would lose hard on their bottom line. Roche even created a small study to give male acne patients reassurance that Accutane had not been found to cause problems with male reproduction, despite the fact that an abundance of adverse drug reaction reports related to sexual side effects had been coming into them and the FDA for many years. The results of this small and meaningless and probably fraudulent study was inserted into a pamphlet titled "What young men/women need to know about acne" and handed out by dermatologists to all patients receiving Accutane. It says,

"One thing you should know about Accutane is that clinical studies have shown that Accutane does not cause any negative effects on the ability to produce normal sperm or on male reproduction……Although you may see special instructions to female patients on the package of Accutane, and on other materials your doctor may give you about Accutane (isotretinoin), these instructions about avoiding pregnancy do not apply to young men. Young men may rest assured that the special instructions for young women to avoid pregnancy do not apply to them."

Liam Grant, chairman of the Ro/Accutane Action Group, gave an excellent detailed presentation at the FDA Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee held on September 19th, 2000. Here are several quotes from his presentation.

"Good afternoon, ladies and gentlemen. My name is Liam Grant. I'm chairperson of an organization called the Ro/Accutane Action Group. Our group was set up in 1997 to provide support for Accutane victims, to investigate all aspects of Accutane from the initial pretrial studies to review the literature, ADR reports, physician guidelines and so on in each country throughout the world where the drug is sold, also to fund and coordinate a series of scientific studies on Accutane to determine the mechanism by which Accutane causes so many severe physical and psychiatric side effects."

"The principal side effects of Accutane based on adverse reaction reports and published studies include general side effects such as photophobia, muscle and joint pain, insomnia, lethargy, central nervous system side effects such as pseudotumor cerebri, which is described as a serious condition involving swelling of the brain, visual disturbances, hearing deficiencies, malaise, drowsiness, amnesia, hallucinations, and psychiatric disorders, which include behavioral disorders, seizures, psychosis, schizophrenia, depression, suicide ideation, suicide thoughts and actions, and also as we all know, it's a teratogen."

"What do scientific literature reports say about Accutane? Well, there are a substantial number of published studies linking the ingestion of Accutane to the emergence of psychiatric disorders as far back as 1983, less than one year after the drug was released onto the market. I've only time to briefly refer to three of these studies."

"The American Academy of Dermatology published a study in 1983 where the authors reported that 5.5 percent of patients experienced depressive symptoms while on Accutane. In the case of one 21-year-old man in that study, the symptoms of depression and forgetfulness were severe enough to cause withdrawal of the drug. So, within a few months of Accutane being introduced,

the first independent study showed that 5.5 percent of patients experienced symptoms within 2 to 3 weeks of starting on Accutane."

"Another published study in 1990 in the same dermatological magazine set out details of serious psychiatric disorders suffered by 7 patients where treatment had to be discontinued because of the severity of the side effects, and they were listed, including manic depression, suicidal thoughts, fear of going insane, et cetera. And remember, that was 1990."

"Another study showed that adverse drug reaction reports for Accutane in the United States in the period from October 1982 to June 1985 represented the highest number of adverse drug reaction reports received by any agency for any prescription drug. It also stated that 22 percent of adverse drug reactions for Accutane relate to central nervous system disorders, such as headache, insomnia, depression, dizziness, personality disorder, and pseudotumor cerebri. Now, that's 1985."

"Sales of Accutane from 1982 to 1985 were very small in the United States because of publicity on the number and serious nature of birth defects caused by Accutane at that time. Accutane at that time had been likened to Thalidomide. So, Accutane with small sales at that time was attracting more adverse drug reactions than any other prescription medicine, despite the fact that some of these other prescription medicines were being sold to not just tens but hundreds of millions of people."

"How many adverse drug reaction reports are there for Accutane? Well, in May 1998 Roche issued a letter to the Irish Medicines Board, which disclosed that there were 40,000 adverse drug reactions on the Roche database in respect of Roaccutane. A review of all ADR data recorded since that time suggests that there may well now be 50,000 to 55,000 such ADR reports for Accutane on the Roche worldwide database."

"Studies show that only 1 in 10 serious ADRs are ever reported. In some countries, it may be only 1 in a 100. If we apply a factor of 10 to the number of adverse reactions recorded for Accutane, we get a figure of 500,000 or more, more than half a million people, which I think gives some idea of the number of people and the scale of suffering caused by this drug."

"Roche have not provided a full list of all ADRs held in the Roche database for Accutane. The FDA and other national agencies have not received this full and detailed list of all ADRs, which I cannot understand. Dermatologists who prescribe this drug on a daily basis have not got the full list of adverse drug reactions worldwide in respect to this drug. Therefore, as I speak, I don't know and I doubt if anyone in this room, apart from the Roche people, knows the total number of suicides worldwide, suicide attempt, and suicide ideations recorded for the drug and also the number, up to tens of thousands, of psychiatric disorders recorded for the drug worldwide."

"I'm just going to briefly mention Norway in reference to a group of 32 very courageous people in Norway who, in 1988, set up an Accutane support group and went to the media to highlight the terrible side effects caused by Accutane. We have the copy of the newspaper reports which are now 12 years out-of-date. They sought from the medical professional to devise proper medical treatment for people who had suffered this severe physical and psychiatric side effects

which are listed in those publications in 1988. As a result of this, the Norwegian Health Authority commissioned a study in 1992. The study was financed by Roche. The final report submitted to the Norwegian Health Authority in 1993 made no reference whatsoever to the scientific publications at that time linking the ingestion of Accutane and the emergence of psychiatric disorders and other items. They did not disclose the number or the nature of adverse drug reactions held on the Roche database at that time."

"Following the increased label warnings introduced by the FDA in February 1998, Roche placed advertisements in the media indicating that Accutane could alleviate depression. That was their reaction. On the 8th of March 1998, the FDA sent warning letters to Roche ordering them to withdraw the promotional material stating that they were false and misleading and promote Accutane for an unapproved use. Roche used similar procedures or maybe tactics in the United Kingdom, but time does not permit me to just deal with those in detail at the moment. Also, Roche used similar advertising tactics in Ireland after the increased label warnings were applied and a feature on that is by Drs. Bickers and Jacobs. And when we looked who were Drs. Bickers and Jacobs, we found that they had been employed by Roche in 1997 in order to try and persuade the FDA not to bring in increased label warnings."

"It came to our attention that Accutane was for sale on the Internet. Now, as far as we can determine -- and we've been monitoring the Internet for many years - the drug was not sold on the Internet prior to the increased label warnings, featuring psychiatric illness and suicide. To investigate the ease with which Accutane could be obtained online, we placed orders under the names of boys and girls in their teens. Within 10 days, we were supplied with the drug from South Africa with a prescription from a doctor with a South African address. Despite the restrictions for the prescribing of Accutane, such as blood tests, pregnancy tests, it is possible to get Accutane without a medical consultation. All you need is a credit card. No medical consultation. No meeting between patient and a doctor. No blood tests. No birth control safeguards. No monitoring of patients."

"Now, Roche profits from sale of Accutane via the Internet could be in tens of millions and perhaps even hundreds of millions of dollars."

"The license for Accutane states that it should only be used for severe recalcitrant cystic acne as a treatment of last resort when all other treatments have failed. And that's the position in most of the countries, if not all of the countries. We believe that more than 80 percent of patients prescribed Accutane have mild or moderate acne, which is in violation of the license. Prescribing doctors should be required to certify that patient's acne is within the license guidelines."

"I'll just mention. There was a survey on several hundred dermatologists, conducted by a professor well-known to this side of the house, which showed that 74 percent of patients were prescribed Accutane for mild or moderate acne. We have other studies in France, and if anybody wants to have a look at them, we would provide them -- showing that between 70 and 80 percent of people prescribed Accutane have mild or moderate acne. Of course, Roche knows that. Everybody knows that. It's produced for severe nodular cystic acne. Unfortunately, the FDA and other national agencies say that they really can't do anything about it. It's the prerogative of the doctor."

"Studies need to be undertaken by Roche or dermatologists to elucidate the mechanisms by which Accutane interacts with the central nervous system and other systems in the body. This will give us an insight into the causes of the specific side effects and hopefully leading to developing proper medical treatment for the tens of thousands, if not hundreds of thousands, of people who have suffered and continue to suffer severe side effects from this drug."

"Patients should have all the proper tests, blood tests, pregnancy tests, and so on which should be properly monitored."

"Sale of Accutane on the Internet should be immediately prohibited."

"Independent studies urgently need to be carried out to establish exactly the mechanism by which this drug causes so many side effects."

"An appropriate medical treatment -- this is probably the most important -- must be devised to counteract the side effects and to provide treatment for the many tens and hundreds of thousands of people who have suffered severe side effects from this drug."

http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3639t2.rtf

There you have it. Even though my report is the most comprehensive and well-documented dossier on Accutane that I know of to date, I'm convinced other studies and information exists out there but they've been suppressed. Independent studies must be immediately carried out in order to confirm and verify Accutane's mechanism of action, that is driving cells toward their Hayflick Limit which I have discussed in-depth in this report, and research also needs to be carried out on the dysfunctional vitamin A and retinoic acid metabolism in former Accutane patients with chronic long-term side effects. People have a right to know how this drug has altered their body down at the cellular level. I don't know if an antidote or a medical treatment exists that can counteract all of the permanent side effects caused by Accutane. There are some treatments that can help certain specific side effects. But if the chronic side effects are indeed a result of telomere shortening induced by Accutane, then these side effects will be permanent unless somebody figures out a way to fix this one major component of the aging process. The everlasting damage caused by Accutane is identifiable with current medical technology, and I've provided some giant clues here in my report to point the scientists in the right direction. For example, has anybody ever bothered to the check the chromosomes (including telomeres and telomerase) before and after a course of Accutane? An enormous amount of research has been devoted to studying vitamin D, another fat-soluble vitamin, which has turned out to be a very safe and effective health enhancing supplement. Now the research ball definitely needs to get rolling with Accutane and vitamin A but this research must not be carried out by Roche, because as Congressman Bart Stupak has said many times and as their criminal history has demonstrated over and over again, they cannot be trusted. A question that arises is what needs to happen to the Roche executives and all the others who are mainly responsible for keeping this toxic crap on the market all these years and handing it out to so many people. I have the answer and it's simple. Find them and throw their asses in jail. This should be a no-brainer because what they've done with Accutane is 100 times worse than any financial crime ever committed by a corporate executive. This is very serious business because we're talking about people's health and their

lives, not their retirement portfolio and personal financial assets. It's time for Roche to be criminally investigated for their unbelievable negligence and outrageous "off-label" promotion of Accutane to millions of people with mild to moderate acne, the evidence is not that hard to find. They are directly responsible for poisoning millions of acne patients with a powerful chemotherapy drug, hiding the evidence of its life-altering dangers, not conducting any research on its mechanism of action, and causing death and permanent injury to thousands of babies, teenagers and young adults all over the world. Everybody is a victim of misinformation because of them, which is why they deserve to be in jail, period. Or better yet, give them this choice. They must choose one of two options. Option number one, they themselves take a 5 month course of Accutane at 80 mg per day. Option number two, they spend the rest of their lives in prison. If they think that Accutane is such a safe nonchalant simple drug that can be handed out to perfectly healthy young people with only a few acne spots on their face or body, then they should have no problem with picking option number one. But I can guarantee that unless they are completely ignorant and oblivious to reality, every single one of them will steer clear of option number one and take the prison time instead, because by having access to all the adverse drug reaction reports, they know for a fact how incredibly devastating the permanent side effects of Accutane can be and this is something they will avoid at all costs.