

When Will the War Be Over? Has the Tipping Point Arrived?

by David Bearman, M.D.

Introduction

Are we finally nearing the end to a long pointless war of hysteria? A war in which we were lied about as to why we entered it. A war that has been particularly hard on minorities. I'm not talking about the Iraq War. I'm talking about a much longer, more insidious, more costly war – the so-called “War on Drugs”.

The Drug War has over 700,000 casualties a year from marijuana arrests alone (80% for simple possession) and many more when the shattered families are added in. The monetary costs are immense, amounting to over 50 billion dollars of our tax dollars per year. Each year for a third of a century, the price tag for lost tax revenues, urine testing, arrests, trials and incarcerations has mounted. Add to this the loss of access to a safe, effective natural medication used by millions of Americans and may millions more patients around the world, the opportunity costs and the priceless cost of our Constitutional protections being shredded and science ignored and we have a crushing price tag.

We may have finally reached a tipping point in this long war on our sanity. We may have come to the spot where cannabis and cannabinoids can rejoin their rightful place in the panoply of therapeutic agents. Science and experience continue to validate the 1937 testimony of then Chief AMA Lobbyist, Dr. William Woodward, that “The AMA knows of no dangers from the medicinal use of cannabis.” Even more importantly the ship of state may finally get back to a full head of Constitutional steam to protect the rights and freedoms guaranteed by the Bill of Rights.

The real issues raised by medical cannabis are Constitutional and philosophical. In this once free country does the individual have the right to care for their well-being or does this pale in comparison to the responsibility of the government to protect us from ourselves. The civil rights battle is crucial to protecting our liberty. Jefferson warned if we let the government control what we put in our bodies, that this was governmental tyranny. Why should the government stand in the way of an individual to take responsibility for their health? Why should cannabis be in a separate category from other herbal remedies?

On the one hand there is the argument that people have a right to self-medicate with a natural product. On the other hand does the 1938 Food, Cosmetics and Drug Act require that the FDA prove the safety of cannabis. Those who say no, the Food, Cosmetics and Drug Act does not confer that power to the FDA, point to the fact that since cannabis has been widely recognized as a medicine for millennia, a person should be able to use cannabis as they would other medicinal herbs, such as saw palmetto, milk thistle, chamomile, and other natural substances on the shelves of pharmacy and natural remedy stores. These are not manufactured and have never been tested nor been given FDA approval. They are plants used for thousands of years by humans. In fact the 1938 law excluded from its reach, products already being marketed. After cannabis was removed from the USP in 1942, it was arbitrarily reclassified by the government as a “new” drug.

More and different questions are on the table now that cannabis is once again being widely recognized as a therapeutic aid. Will European companies dominate the field of cannabinoid chemistry? Will patients be able to produce their own medicine in competition with corporations? If there is this competition, will individuals or corporations prevail or can they coexist? Whatever happens regarding the emerging issue of medicinal cannabis and cannabinoids, we are reaching the tipping point toward broad legal acceptance of medicinal use of cannabis and cannabinoids.

Seven Signs We're Reaching a Tipping Point Legalizing Medicinal Cannabis

The U.S. is tipping toward a more reasonable policy regarding therapeutic and recreational substances. There are at least seven (7) signs we are reaching this drug control public policy tipping point.

- The December 2005 FDA approval of GW Pharmaceuticals phase III clinical trials for tincture of cannabis.
- Former drug warriors Bob Barr and Dr. Barthwell becoming spokespeople for MPP & GWP, respectively.
- Hinchey – Rohrbacher Amendment gaining more votes.
- University of Massachusetts Prof. Craker winning his suit before a DEA ALJ charging the DEA with supporting a marijuana growing monopoly. The ruling directed the DEA to issue Dr. Craker a license to grow cannabis for research.
- ASA lawsuit against HHS for violating the Data Quality Control Act of 2002.
- Governor William Richardson (NM) a Democratic Presidential candidate, signs medicinal cannabis bill and was not adversely affected politically.
- The ten-year history of the relegation of medical cannabis and its documented approval by over 5,000 U.S. physicians.

These events and actions illustrate American's dramatic change in attitude about the efficacy of cannabis. They are favorable influences on public opinion and public policy.

FDA / GW / Clinical Trial

A British Company, GW Pharmaceuticals, has been doing clinical research on tincture of cannabis since 1999. They have done numerous research studies in the UK and Spain on the efficacy of their tincture of cannabis product (Sativex) for relief of muscle spasm and pain from multiple sclerosis and relief of neuropathic pain. The research was compelling enough for Sativex to be approved for sale in Canada by Health Canada (the Canadian equivalent to the FDA) in April 2005. Bayer AG has been marketing Sativex in Canada to doctors and pharmacists since June, 2005.

GW then hired the former top doctor in the "Drug Czar's" office, Dr. Andrea Barthwell, to lobby the FDA. It paid off. In December 2005, the FDA approved a Phase III clinical trial to determine if cannabis was effective in relieving intractable pain in cancer patients. Completion of this study is projected for early winter, 2008.

Drug Warrior Conversion

Former drug warriors such as Dr. Barthwell and one-time Republican Georgia Congressman, Bob Barr, are now lobbyists for legalization of marijuana and tincture of

cannabis. Dr. Barthwell, the doctor who on the Montel Williams show, stated in front of at least four (4) medical marijuana patients that marijuana has no medicinal value, is now a paid lobbyist for GW. She is still tap-dancing though. She says that tincture of cannabis is not liquid marijuana. I'm willing to agree with her so long as she tells me what it is.

Barr may be remembered for the aptly named Barr Amendment. This 1997 legislation barred the expenditure of federal funds to count the votes in the District of Columbia for a local D.C. initiative legalizing medical marijuana. Now he's a paid lobbyist for the Marijuana Policy Project (MPP), an organization whose goal is to legalize the recreational use of marijuana.

Barr, no longer either a Congressman or a Republican, attributes his change of heart to his being appalled at the federal government's opportunistic power grab since 9/11. He recognizes that the federal drug laws have removed many of our historical protections on freedom of speech, illegal search and seizure, self-incrimination, states rights and limits to the reach of the federal government – the 1st, 4th, 5th, 9th, and 10th Amendments to the Constitution. Drug prohibition is hobbling our Constitutional protections against government invasion of our historic American Freedoms and Rights.

Hinchey – Rohrbacher Amendment

For four years Hinchey, a very liberal New York Democrat, and Dana Rohrbacher, a libertarian leaning California Republican, have co-sponsored an amendment to the Department of Justice Budget Act. This amendment would prohibit expenditure of federal funds to enforce federal marijuana laws in those states which have relegalized medical cannabis. Each year it has received more votes. Last year it garnered 163, still a far cry from the 218 required to assure passage.

It is strongly anticipated that it will receive many more votes this year for two reasons: (1) 38 House members who did not support this amendment last year were not returning to Congress. Most were Republicans who were replaced by Democrats. Since roughly 70% of Democrats have voted for the bill in the past, we can expect an additional 24-26 votes from that change. (2) Several Congressmen and women last year said, off the record, that while they supported the content of the bill, they would not vote for it because 2006 was an election year. Most of these legislators should vote for it this year. So without any additional lobbying from groups like Marijuana Policy Project (MPP), Drug Policy Alliance (DPA) and Americans for Safe Access (ASA), this amendment should easily top 200 votes; closing in on the 218 required to guarantee passage.

• Presidential Candidate Signs Legislation Legalizing Medical Marijuana

In May 2007, Democratic Presidential Candidate, Governor Bill Richardson of New Mexico signed a medical marijuana bill into New Mexico state law without apparent political damage and some possible political gain. This should make it easier for Congress to have the legislative courage to vote for the Hinchey-Rohrbacher Amendment. Most House watchers would not be surprised to see the yes vote approach 200 votes with an outside chance for more.

• Suit to Prevent DEA from Blocking Studying the Constituents of Cannabis

For years the DEA has squelched legitimate medical cannabis research by limiting researchers' access to legal research grade marijuana. This leaves researchers – and the 12 states that have so far approved marijuana for medical purposes – in a Catch-22. Drug warriors object that there is no research demonstrating marijuana's efficacy while at the same time preventing such research from being done.

University of Massachusetts Professor Albert Craker, an expert on medicinal plants, along with MAPS recently sued the DEA for denying Craker a license to grow marijuana. He wants to grow and study various strains of cannabis to discover which chemicals or combination of chemicals in cannabis are most effective in treating the various diseases cannabis provides relief for.

This Spring the DEA's Chief Administrative Law Judge (ALJ) Mary Ellen Bittner ruled for Craker and MAPS. The ALJ found that the DEA was guilty of suborning an illegal monopoly by the University of Mississippi to grow marijuana. Judge Bittner recommended to the head of the FDA that the DEA be ordered to grant Professor Craker a license to grow cannabis. If this ruling stands, Dr. Craker will be studying different strains of cannabis and compete with the government's marijuana growing monopoly. His research would also help identify possible cannabinoids for pharmaceutical use.

If the FDA Director does not overturn this decision, the DEA's stranglehold on medicinal cannabis research in the U.S. will be loosened. If implemented by the FDA, this ruling will finally make research grade cannabis available to medical researchers. This will give U.S. scientists a much better opportunity to unlock the mysteries of the endocannabinoid system and a shot at catching up with such research in Canada, England and Europe.

ASA Data Quality Control Act

In 2003 Americans for Safe Access (ASA), an advocacy group for medical marijuana patients, filed suit against HHS for violating the Data Quality Control Act (DQCA) of 2002. This law was passed with lobbying from the U.S. Chamber of Commerce, Chevron and Phillip Morris and other large corporations. The Data Quality Control Act requires that information used and disseminated by certain federal departments and agencies meet standards for "quality, objectivity, utility, and integrity of information".

The law has been used by industry, specifically the Center for Regulatory Effectiveness to challenge so-called "junk science" which the government used to support health and environmental regulations. In 2004 the Washington Post noted that 39 DQCA challenges had been made, 32 filled by industries or industry organizations.

ASA wrote in their brief, "The U.S. Department of Health and Human Services (HHS) repeatedly misstates the scientific evidence and ignores numerous reports and studies demonstrating the medical utility of marijuana and its constituent compounds. **In particular, ASA challenged HHS statement that marijuana "has no currently accepted medical use in the U.S."** As evidence, ASA cited the government funded IOM report that clearly acknowledged the medical benefit from cannabis and cannabinoids. ASA asserts that disseminations of these scientifically inaccurate statements violate the Data Quality Control Act standards which require lack of bias, consistency, and disclosure of the underlying rational basis for an agency's conclusion.

By law the government is required to timely respond to the allegations with their scientific source of the disputed statements. HHS has not done so. First they did not respond within the legal time limit. **Then, rather than respond with documentation of their science, HHS' official response was "we are not going to respond." So to date, HHS is out of compliance with the DQCA. ASA has sued HHS a second time for violating the process of the DQCA. The case is now in the 9th Federal Circuit Court. The U.S. Chamber of Commerce and several Fortune 500 companies have indicated interest in filing amicus briefs for ASA in this matter.**

- Physician Experience

The State of Oregon keeps official data on the number of physicians who make medical marijuana recommendations. So far over 2,500 Oregon doctors have done so. In California the figures can only be estimated but the number easily exceeds 3,500. The conditions for recommendations include chronic pain, migraines, nausea, seizures. The mounting research and patient reports are seeing more doctors open their minds to the possibility of medicinal cannabis.

Is This the Turing Point?

It is clear to all but the most scientifically illiterate that cannabis and cannabinoids are medicine. Many informed observers believe that the future of medical marijuana lies with classical pharmacological drug development. While others champion individual responsibility. Still others see both options existing side by side.

There is great interest in the pharmaceutical industry in developing new drugs that can treat the constellation of symptoms for which cannabinoids might and/or do have therapeutic benefit. Several companies are producing various synthetic cannabinoids and GW continues to do research on a wide range of additional clinical applications for their product Sativex and their other strains of cannabis.

In the 21st century we will see greater understanding of brain chemistry. The role of the endocannabinoid system, the largest neurotransmitter system in the brain, will be much better understood. We will have metabolic blockers which prolong the half-life of the brain's naturally occurring cannabinoid, anandamide. More anandamide (one of the brain's natural cannabinoids) antagonist agents, such as the weight loss drug, Rimonabant, will be created. We will see development of different strains of cannabis which can be used for specific disease entities. Scientists will isolate different chemical components of the plant. More synthetic cannabinoids will be invented, researched, approved and marketed.

The future is bright for greater therapeutic applications of cannabis and cannabinoids. Dr. Steven Hosea, Santa Barbara infectious disease doctor, and winner of the 2005 Santa Barbara News Press Lifetime Achievement Award for his work in treating AIDS patients, has said in support of the use of medicinal marijuana, "A physician's mission is to heal illness, alleviate suffering, and provide comfort for the sick and dying." Thousands of American doctors know from patient reports that cannabis is both therapeutic and has few side effects. In 1988 Chief FDA ALJ Francis Young wrote after a 2-year hearing that marijuana was "one of the safest therapeutic agents known to man."

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Medical Cannabis

The Science

As time has gone on, we've discovered more about the chemistry of both the cannabis plant and the endocannabinoid neurotransmitter system (characterized by Dr. Raphael Mechulam, Professor of Jerusalem University in 1992). Cannabis contains 483 chemicals. In addition to THC (characterized by Prof. Mechulam in 1964), the cannabis plants has over 60 cannabinoids. Cannabinoids are 21 carbon molecules which are attracted to specific receptors in the brain. The most pharmacologically active is delta 9-Tetrahydrocannabinol or THC for short. Other C21 compounds include cannabidiol (CBD) and cannabinol (CBN). CBD has no psycho-active capability however CBN is a mildly psycho-active chemical. Tetrahydrocannabivarin (THCV) and cannabichromene (CBC) are also important cannabinoids. Cannabis also contains six essential oils, at least eight alkaloids, flavonoids and sugars. (726) (Cannabis: Booth, pg. 7 and (726a) Russo & Grotenhermann. Several cannabinoids and some phenoids and flavinoids have been found to have therapeutic value. (725) (Cannabis and Cannabinoids edited by Russo & Grotenhermann)

The Conditions

The list of conditions cannabis helps provide treatment and relief for continues to expand. In 1995 *The Lancet* list relief of nausea, analgesia, glaucoma, and appetite stimulation. The 1997 House of Lords Science and Technology Report had a longer list which included _____. The 1999 U.S. government funded Institute of Medicine (IOM) report concluded that THC is an analgesic, muscle-relaxant, anti-depressant and anti-emetic agent. Some other chemicals in the plant may also contribute to cannabis' therapeutic effects. Clinicians and researchers have demonstrated that cannabis is also useful in treating ADD/ADHD, OCD and PTSD. (xx) (O'Shaughnessy's) Cannabis can reduce epileptic fits (xx)(?), stimulate appetite (xx)(NORML), and dilate bronchial tissue (xx)(Tashkin). It's helpful in treating ulcerative colitis, IBS, and Crohn's Disease. Recently it's been shown to be of help in alleviating some symptoms of Alzheimer's and slowing the progressive neurological deterioration. (727) (O'Shaughnessy's)

Compared to other recreational drugs including coffee, cannabis is considered by experts to be the safest. A 1994 New York Times article cites work by Jack Henningfield of NIDA and Neal Benowitz of the University of California at San Francisco (UCSF). Henningfield and Benowitz rated the addictive symptoms of cannabis vs. other commonly used drugs including heroin, alcohol and cocaine. Overall, 'Marijuana was ranked lowest for withdrawal symptoms, tolerance and dependence (addiction) potential; it ranked close to caffeine in the degree of reinforcement and higher than caffeine and nicotine only in the degree of intoxication.' (xx) (Henningfield and Benowitz, 1994). Noted cannabinologist and neurologist Dr. Ethan Russo, points out that, "Even in cases of high daily intake, such as the 94-day cannabis study (Cohen 1976), any withdrawal symptoms on its sudden cessation were transient and mild." (xx) (Medical marijuana pro/con website)

