

Prop 19: Indifference to Public Health

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Proposition 19 on the November 2, 2010 California statewide ballot asks the people of California to permit the state to legalize marijuana, collect taxes on its sale, and apply tokens of face-saving regulations. With windfall profits in store, the proponents have shaped the legalization argument stating that it would (1) help to offset California's budget deficit, (2) cut into profits of violent drug cartels, and (3) free law enforcement resources to focus on more dangerous crime. Rigorous scrutiny can dismantle each of these arguments. Tactic (3) is recognizable from earlier use in the marijuana decriminalization (Prop. 2) debate in Massachusetts. It was featured in hourly TV ads narrated by an allegedly well-reimbursed former policeman. Massachusetts district attorneys informed me that after careful analysis of the scant number of arrest records for marijuana possession, no credible evidence could be found that law enforcement was being diverted away from serious crimes, because they were occupied with arresting people in possession of small personal quantities of marijuana - none. Two years ago, the Democratic Massachusetts Attorney General Martha Coakley and I shared a podium to speak in opposition of Prop 2. A few weeks ago, Attorney General Eric Holder weighed in on Prop 19 by stating that, regardless of how California votes, Federal anti-marijuana laws will be enforced. His appropriate response, however, is compromised by his refusal to enforce Federal laws regulating "medical marijuana".

Propaganda can be effective. In 1996 it convinced Californians to approve Prop. 215 and its heir SB420 which allowed for a smoked (!!) leaf of unknown chemical composition, unregulated doses of psychoactive ingredients, and hundreds of other potentially hazardous chemicals to treat serious medical conditions including "AIDS, anorexia, arthritis, cachexia, cancer, chronic pain, glaucoma, migraine, persistent muscle spasms, seizures, epilepsy, severe nausea, any other chronic or persistent medical symptom that substantially limits the ability of the person to conduct major life activities". The most obvious objection to passage was the use of smoking as a delivery system, after a 40 year campaign to stop smoking. The second objection was the poor quality of evidence (or no evidence) for marijuana's safety and efficacy. A few years after Prop 215 passage, Governor Davis funneled millions of dollars into medical marijuana research to seek validity for these "ballot-approved" medical claims. After a decade of funding, this California Center for Medicinal Cannabis Research has issued 24 publications. Only four were clinical studies that examined the medical indications stated in the ballot initiative, and these recruited only experienced marijuana users. One conscientious study recorded the side effect profile of marijuana: patients reported pain reduction, but also reported feeling high, being impaired, feeling sedated, and showed cognitive impairment in learning, speed recall, and attention. Five major clinical studies were discontinued because the investigators could not recruit enough patients to study marijuana effectiveness for cancer pain relief, muscle spasticity, multiple sclerosis, severe nausea and vomiting, and neuropathic pain. The third objection is that Californians, in electing to vote in favor of this "medicine" (Prop 215), circumvented stringent FDA standards, a measure that threatens our elaborate and sophisticated drug approval system. FDA standards have protected Americans from fraudulent, dangerous or ineffective drugs for decades with an approval system, although imperfect, that is among the most rigorous in the world. Consider the wise FDA response to ballot initiatives for the sham cancer treatment laetrile and denial of approval for thalidomide and a host of other unacceptable drugs. Circumventing FDA approval by a ballot initiative is a dangerous, slippery slope that can create chaos in the approval process for evidence-based medicines. The FDA requires that a new drug is a pure compound, its chemistry, manufacturing, and composition of matter are tightly controlled so that each batch is identical, that its production methods are validated, that its pharmacology and toxicology in animals is known, and that its rate of entry, bioavailability, toxicology, microbiology, dose response, efficacy, safety, side effect profiles are documented. After approval, case reports and safety updates are required to be submitted to the FDA for ongoing evaluation.

The practice of medicine increasingly is evidence-based, but marijuana has no academic presence in medical training; there is no requirement to extract medical history or give a detailed medical exam, discuss long term treatment, effects, or follow-up, provide informed consent, consult with other physicians, keep proper records that support recommending marijuana instead of safe approved alternatives, have a good faith relationship with patient rather than a "marijuana mill", or be able to identify substance abusers or the addicted. Dispensaries had no product liability, no product regulation, no chain of custody, no accountability. At the time the ballot passed, was marijuana's scientific record sufficient to fulfill FDA's rigorous standards of safety, efficacy, and side effect profile? Was smoked marijuana a safe and effective treatment for over 12 diseases, including the myriad forms of chronic pain that respond uniquely to different class of drugs (e.g.

non-steroidal anti-inflammatory, steroids, GABA-based, opioid drugs)? The smoked marijuana leaf does not even begin to meet acceptable standards.

Fourteen years later Californians face another ballot initiative, with the same strategies used in passing Prop 215. It is not accidental that the legalization bill landed in California. A well-funded itinerant machine has traveled from vulnerable state to state, using propaganda to overturn evidence-based Federal laws and regulations that are shaped by well informed professional judgment. Normalization of marijuana use via a "medical" moniker was a tactic to drive the incremental process in California, a receptive state that takes great pride in leading social change in America. Prop 215 ignored the paucity of science. Prop 19 ignores the abundant science. Prop 19 focuses on law enforcement, crime, and tax windfalls, but the mammoth in the room - public health, the potential for creating unacceptable human suffering and disproportionate taxpayer costs - is ignored. Even Prop 19 opponents, with their focus on public safety, workplace, and federal funding, do not fully address a critical spectrum of marijuana-related health issues. Personal and public well-being have been the primary motives driving marijuana laws. Maintaining these laws are more compelling than ever, as marijuana potency and availability soar, in parallel with escalating scientific evidence of marijuana's adverse consequences. Unlike opioids, marijuana is not likely to cause death by overdose, but it resides in Schedule I because of its high abuse liability, intoxicating properties, and no medical indications - essentially because it adversely affects brain function and biology. As an intoxicant, a Saturday night marijuana binge can have residual cognitive deficits on learning and memory for several days (marijuana research protocols generally wait at least 5-30 days for marijuana to clear before measuring its long term residual cognitive effects). These deficits are readily quantified, exaggerated in schizophrenics, and should refute the advocates who expound the benefits of marijuana for Alzheimer's diseased patients. The 2009 National Highway Traffic Safety Administration (NHTSA) showed that more people are driving weekend nights under the influence of marijuana (8.3%) than alcohol (2.2%). It is unacceptable for airline pilots, marines, physicians, nuclear power plant operators, or policemen to be impaired on the job but acceptable for drivers, teachers, day care providers, construction workers, students, nurses, or miners? Emergency department mentions of marijuana in the US have increased from 281,619 to 374,435 during 2004-2008, in parallel with linear increases in marijuana potency and marijuana addiction. With the California population at 12% of the nation's population, marijuana conceivably can add at least \$60 million (in 2004 dollars) to ED health care costs.

Are there enduring effects of marijuana? Marijuana is addictive for about 9-10% of users, and progression to addiction is more rapid than progression to nicotine addiction. Abstinence in the heavily addicted unmasks physical and psychological neuroadaptation, manifest by an unnerving withdrawal syndrome. Nationwide, more people have a medical (DSM-IV) diagnosis of marijuana abuse/addiction than for any other illicit drug, and more youth are DSM-IV positive for marijuana than for alcohol. Extrapolating from national statistics, a parsimonious estimate is that half a million people in California harbor a DSM-IV diagnosis for marijuana addiction/abuse. With an average cost of \$4,000 for addiction treatment in an ambulatory setting and at least four times that amount for residential care, this can add an estimated \$2 billion in marijuana treatment needs for California annually. The addiction rates of marijuana are 6-fold higher in youth who initiate marijuana use at age 14 or younger. In a perfunctory token to concerned citizens, Prop 19 attempts to wall off youth from marijuana access. Yet there is no reasonable evidence that California will effectively block marijuana use by young adolescents. Our abysmal failure at preventing youth from smoking cigarettes should be our intuitive guide. Early onset of marijuana use is also associated with addiction to other drugs in adulthood, including alcohol and heroin. This phenomenon can be explained away by a host of factors, genetics, social environment, poverty, child abuse, or psychiatric conditions. But how to explain that rats exposed to the most active constituent of marijuana, delta-9-tetrahydrocannabinol or THC, *only during adolescence*, seek heroin at higher rates after they mature into adults and display a fundamental change in brain opioid systems long after their last dose? Social, environmental, poverty, child abuse, or psychiatric conditions do not apply to inbred rats - in this case the drug alone alters the trajectory of brain and behavioral development.

A link between marijuana use and neuropsychiatric disorders is developing. In population studies of more than 75,000 people from seven different countries, early marijuana use was found to be associated with an average two-fold higher risk for later-onset psychosis and schizophrenia in vulnerable populations. The influential medical journal *Lancet*, which declared in 1995 that "The smoking of cannabis, even long term, is not harmful to health" changed this conclusion in 2007 by stating that "Research published since 1995, including [the] systematic review in this issue, leads us now to conclude that cannabis use could increase the risk of psychotic illness... governments would do well to invest in sustained and effective education campaigns on the risks to health of taking cannabis." A current debate is being waged on whether to revise comparative risk assessment in the Global Burden of Disease (GBD) to include the attribution of psychosis to marijuana use. Degenhardt et al argue that the risk assessment should be included because the evidence is as good as that for many other risk factors in the GBD. Some scientists have estimated that marijuana contributes about 8% to new cases of schizophrenia. If this estimate is accurate, unfettered marijuana access in California conceivably would add 25,000+ cases of schizophrenia, with a lifetime estimated cost of caring for this cohort in excess of \$6 billion (based on a low estimate of \$8,000/per patient/year, for 30 years).

Heavy daily marijuana use across protracted periods can exert harmful effects on brain tissue and mental

health. Brain imaging of long-term heavy marijuana users has shown exposure-related structural abnormalities in brain regions critical for learning, memory and emotional responses, with changes associated with impaired verbal memory and other symptoms. Abnormal brain size and circuitry in brains of adolescent marijuana users have also been documented recently. Compromised academic performance, school drop-out, and a host of other adverse consequences are elevated in high school and college students who use marijuana. Accurate price tags for these lost educational and employment opportunities don't exist, but at the very least, they should weigh heavily on the voter's conscience. Peripheral health is also affected, as marijuana use is associated with increased risks for bronchitis, compromised pulmonary function, precancerous lung changes, cardiovascular events, problematic pregnancies, and teratogenic and hormonal effects.

Despite this evidence, 2009 was a banner year for marijuana use in our nation. Compared with 2008, in 2009 1.5 million more marijuana users were added to the ranks. The steady decline in marijuana use among youth over the past 6 years was reversed in 2009. Marijuana use among 12-17 year olds increased by over 7%, with a 14% increase among boys and a 13% increase among college students. Expanding acceptance of medical marijuana, reduced perception of harm, and proliferating availability conceivably are driving a pivotal upward swing in use. Imagine the impact of Prop 19 approval on California use/addiction/health/psychosis/school performance statistics in the coming years!

The commercials on TV and editorial support of Prop 19 are misguided and misleading. Who are the real beneficiaries from normalization of marijuana use? Intelligent California voters will perform due diligence, examine the biomedical literature on marijuana (e.g. NIDA: <http://drugabuse.gov/infoacts/marijuana.html>), and make evidence-based decisions. Californians have a unique opportunity to display to the nation and to bewildered citizens of other countries that they do not base important decisions on seductive propaganda.

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