EXHIBIT A

ABC NEWS

Obama: 'Rigid Ideology Has Overruled Sound Science'

Obama Signs Two Environment Memos, Pushes EPA to Allow States to Set Emissions

By JAKE TAPPER and HUMA KHAN

Jan. 26, 2009—

Continuing efforts to overturn more of the last administration's policies, President Obama signed a presidential memorandum today requesting the EPA consider approving a waiver that will allow 14 states to set their own stricter automobile emissions and fuel efficiency standards.

In 2007, then-Environmental Protection Agency Administrator Stephen Johnson denied California and Arizona, Connecticut, Maine, Maryland, Massachusetts, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington and New Jersey -- the right to set their own clean air standards, despite staff scientists' recommendation to do so.

"California has shown bold and bipartisan leadership through its effort to forge 21st-century standards, and over a dozen states have followed its lead. But instead of serving as a partner, Washington stood in their way," Obama said.

Obama also signed a memorandum directing the Department of Transportation to expedite finalization of more fuel-efficient standards for the auto industry to cover 2011 model-year cars.

Last May, the Bush administration informally proposed increasing the standard to an average of 27.8 miles per gallon on average fuel economy standards for passenger cars and light trucks for models 2011 through 2015, and Obama will likely increase that.

Flanked by Transportation Secretary Ray Lahood and EPA administrator Lisa Jackson, Obama described U.S. dependence on oil as "one of the most serious threats that our nation has faced," comparing it to the dangers of dictators and terrorists.

"For the sake of our security, our economy and our planet, we must have the courage and commitment to change," Obama said at the event held in the East Room of the White House. "We need more than the same old empty promises."

The final EPA decision could take several months, but it's a step toward allowing states more freedom in guiding their path to environment standards.

The president also pushed his American Recovery and Reinvestment Plan, saying that it would "save taxpayers $2 billion a year by making 75 percent of federal buildings more efficient."

Both of Obama's memoranda are written with cautious legalese and assiduous attention to process. But

however soft they may seem, they are expected to lead to dramatic changes in environmental policy from the Bush administration.

In 2007, Congress passed the Energy Independence and Security Act, designed to create more energy independence and security in the United States, ramp up production of clean renewable fuels and improve energy efficiency. But environmentalists criticized the Bush administration for not doing enough to follow through on these goals.

Reaction to Obama's Moves

Obama's move today paves the way for states to eventually impose much stricter fuel emissions standards and for the federal government to require that U.S. automakers produce far more fuel-efficient cars and trucks much quicker than Bush would have required them to do so.

Given that these states -- especially California -- command a large market share, allowing states to set their own standards is likely to have a significant impact on the U.S. economy.

The reversal received a mixed reaction.

As expected, environmental groups hailed the announcement as a "thrilling moment," and one that will leave "behind our failed fossil fuel policies."

Florida Gov. Charlie Crist, a moderate Republican, applauded Obama's request to Jackson, even though Florida is not one of the states in line to get a waiver, but he added that "The waiver is a critical aspect for California, Florida and 17 other states which have adopted, or are in the process of adopting, automobile emissions standards."

California Republican Gov. Arnold Schwarzenegger also praised the move, saying in a written statement that, "With this announcement from President Obama less than a week into his administration, it is clear that California and the environment now have a strong ally in the White House. Allowing California and other states to aggressively reduce their own harmful vehicle tailpipe emissions would be a historic win for clean air and for millions of Americans who want more fuel-efficient, environmentally friendly cars."

California sought to reduce greenhouse gas emissions from passenger vehicles by 30 percent by 2016, but its request for a waiver was rejected by the former Republican administration.

Other Republicans were not so happy. House Minority Leader John Boehner, R-Ohio, said the decision could hurt American jobs, given Detroit's struggles.

"The president's action today is disappointing," Boehner said. "The effect of this policy will be to destroy American jobs at the very time government leaders should be working together to protect and create them. Millions of American jobs will be placed in further jeopardy if automakers are forced to spend billions to comply with potentially dozens of different emissions standards in dozens of different states."

The U.S. Chamber of Commerce also criticized Obama's memoranda.

"At a time when we need to jump start our economy, regulating CO2 in this manner would stop most of President Obama's stimulus proposal cold in its tracks and create a regulatory train wreck," William

Kovacs a vice president at the U.S. Chamber of Commerce, said in a statement. "In addition, such a move would put the EPA one step closer to making carbon dioxide 'subject to regulation' under the Act. This would ... have the unintended consequence of creating costly and burdensome permitting requirements on millions of construction projects, including hospitals, schools, and office buildings."

Obama's memoranda today bear few surprises. The president has reiterated that energy and environment issues will be a top priority in his administration, and today's actions affirm he will invest some of his time and political capital into this issue.

"He feels the need to get moving in some areas where he thinks things can be done relatively soon," said Michael A. Levi, senior fellow for energy and environment at the Council of Foreign Relations.

This may be a welcome move to many Americans. In an ABC News/Washington Post poll, 41 percent of Americans said clean power should be the "highest priority" item in stimulus spending.

But Obama's push to create more fuel-efficient cars domestically and boost the economy through his stimulus package comes at a time when automakers continue to struggle to keep their operations and layoffs continue to deter the financial climate.

In Detroit, the hub of U.S. auto manufacturers, the reaction was mixed, with some saying that auto companies need to make this happen and others arguing that manufacturers would be forced to pass down the costs of meeting these regulations to consumers.

Just two months after the Big 3 automakers came to Washington, D.C., requesting a bailout and promising more fuel-efficient vehicles, the state of automakers remains weak. General Motors said today that it will cut 2,000 jobs at plants in Michigan and Ohio because of slow sales. Changing its strategy so it falls in line with the government may not be as easy as in a better financial climate.

Job cut announcements -- some of which Obama addressed -- also flowed in today. Home Depot Inc. said it plans to eliminate 7,000 jobs while closing four dozen of its smaller home improvement stores. Sprint Nextel Corp. said it is eliminating about 8,000 positions as it seeks to cut annual costs by $1.2 billion.

Changing Directions

Obama has swiftly moved to reverse several other Bush-era policies.

Last week, he signed an executive order to shut down the controversial detainee center at Guantanamo Bay within a year's time.

He also overturned the "Mexico City policy" and opened the way for federal funding to flow to international organizations that provide abortion-related services, a Reagan-era law that was overturned by President Clinton and then reimposed by Bush.

Obama, who is also in the process of pushing his stimulus plan, met with Republican leaders last week to discuss the economic package. But despite the bipartisan approach, Obama showed there were clear limits.

And Monday, in another symbolic turn from the Bush administration, Obama appointed as his special envoy for climate change Todd Stern, the U.S. negotiator on the Kyoto Protocol agreement that the Bush

administration withdrew from in 2001.

In a subtle criticism of presidents past, Obama stated in his remarks today that alarms about energy dependency have been sounded, but that no concrete measures have been taken.

"Year after year, decade after decade, we've chosen delay over decisive action. Rigid ideology has overruled sound science. Special interests have overshadowed common sense. Rhetoric has not led to the hard work needed to achieve results," he said. "Our leaders raise their voices each time there is a spike in gas prices, only to grow quiet when the price falls at the pump."

But despite his early steps, going beyond rhetoric may be a challenge for the new administration as well.

"I'll be looking to see whether the president can use his ability to communicate in order to build the political support that's necessary to do what we've known for long that are important," Levi said. "Ultimately, big steps to change the way we use energy are going to require tough decisions from congressmen, and those are not going to happen without presidential leadership."

With a myriad of issues -- from the economy to two wars abroad -- facing the newly minted president, it remains to be seen how Obama's energy and environmental agenda will unfold in the coming years.

The Associated Press contributed to this report.

EXHIBIT B

THE BRIEFING ROOM

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 9, 2009

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Scientific Integrity

Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

By this memorandum, I assign to the Director of the Office of Science and Technology Policy (Director) the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The Director shall confer, as appropriate, with the heads of executive departments and agencies, including the Office of Management and Budget and offices and agencies within the Executive Office of the President (collectively, the "agencies"), and recommend a plan to achieve that goal throughout the executive branch.

Specifically, I direct the following:

1. Within 120 days from the date of this memorandum, the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles:

(a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;

(b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;

(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

(d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and

(f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

2. Each agency shall make available any and all information deemed by the Director to be necessary to inform the Director in making recommendations to the President as requested by this memorandum. Each agency shall coordinate with the Director in the development of any interim procedures deemed necessary to ensure the integrity of scientific decisionmaking pending the Director's recommendations called for by this memorandum.

3. (a) Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

4. The Director is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

FEB - 1 2000

Ethan Russo, M.D.
Western Montana Clinic
515 W. Front Street
Missoula, Montana 59807

Dear Dr. Russo:

The Public Health Service (PHS) has completed the review of your protocol, "Cannabis in Acute Migraine Treatment." Enclosed please find a copy of the Summary Statement assessing the scientific merit of the proposed research design, the roster of members of the committee, and the scientific review criteria. The scientific review was conducted by the Center for Scientific Review (CSR) of the National Institutes of Health on behalf of the PHS. After consideration of the Summary Statement, the PHS has determined that it cannot provide marijuana for the research as proposed. However, if the changes recommended by the CSR review group are incorporated into a new, revised protocol, the PHS will reconsider your request.

Specifically, the PHS has determined that the following changes should be made to the protocol:

1. A placebo arm should be included. Specifically, it is recommended that subjects be randomly assigned to one of three study groups: placebo Marinol – active THC cigarette; active Marinol – placebo cigarette; and placebo Marinol – placebo cigarette. Sumatriptan should not be administered except as a rescue medication.

2. If adequate numbers of subjects can be recruited, in order to avoid the significant threats resulting from attrition, each subject should be recruited for three sessions (one session for each condition, in random order) rather than for an open 3 month period. If adequate numbers cannot be recruited for such a design, PHS would be interested in other proposed methods to address the anticipated subject attrition problems.

3. Marinol and marijuana administration should be adjusted to assure equivalent doses of THC are administered.

4. To maximize the probability that the subject blinding will not be compromised, the timing of administration of Marinol and THC should be adjusted so that peak blood concentrations and psychoactive effects occur at approximately the same time.

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5. International Headache Society trial guidelines should be incorporated into the study design as they affect inclusion criteria, baseline measures, types of migraine studied, treatment effectiveness measures, patient safety, and adverse reactions.

6. The consent form should be modified consistent with the recommendations of the CSR review group.

If you agree to revise your research protocol to address these issues and recommendations, please send a revised protocol, copies of all instruments, and a revised consent form to me. I will forward the information to the PHS, and PHS will at that time make a determination regarding the adequacy of the revisions in addressing the recommendations.

Sincerely,

Steven W. Gust, Ph.D.
Special Assistant to the Director

Enclosure

SUMMARY STATEMENT
(PRIVILEGED COMMUNICATION)

2RG1 NAR1-1
Review Group: CENTER FOR SCIENTIFIC REVIEW SEP
Meeting Dates: IRG: November 1999 COUNCIL: Jan/Feb 2000

RUSSO, ETHAN, MD
WESTERN MONTANA CLINIC
515 W. FRONT ST.
MISSOULA, MT 59807

Project Title: CANNABIS IN ACUTE MIGRAINE TREATMENT PROJECT

IRG Action: REQUEST DENIED
Human Subjects: 32 - HS INV - CERTIFIED, IRG COMMENTS
Animal Subjects: 10 - NO LIVE VERTEBRATE ANIMALS INVOLVED
Gender: G4U - GENDER COMPOSITION UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
Minority: M4U - MINORITY COMPOSITION UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
Children: C4U - CHILDREN COMPOSITION UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
CLINICAL RESEARCH - NOT NIH-DEFINED PHASE III TRIAL

BUDGET NOTE

RESUME AND SUMMARY OF DISCUSSION: This protocol aims to compare the effectiveness of smoked marijuana and oral tetrahydrocannabinol (THC), as treatments for pain and nausea associated with migraine headaches. A secondary goal is to assess change in frequency and severity of migraine headaches related to periodic use of these substances. The application is clearly written and addresses an important public health problem. There is an unmet need for effective migraine treatment and the investigator suggests the possibility of using cannabis or marijuana. While demonstrating efficacy for marijuana in treatment for migraine might be of value, the reviewers emphasized that no conclusion can be drawn about the efficacy of the THC or marijuana for the treatment of migraines in the sample being studied based on a fatally flawed study design. Additionally, the study design and its implementation do not comply with the recommended trial guidelines of the International Headache Society which significantly limits the possibility of obtaining usable information. Reviewers were also concerned that the principal investigator has very little experience with the conduct of clinical trials, and therefore could not appreciate how complicated it is to successfully design, recruit, and run these studies. Other concerns were that the study was not truly blind; there was no placebo control group; and the rescue medication proposed was not the best choice. Overall, the committee agreed unanimously that the level of scientific merit of this application does not warrant provision of the requested resources by the NIH.

Description (adapted from investigator's abstract): Rationale: Cannabis, or marijuana, has been used for centuries for both symptomatic and prophylactic treatment of migraine. It was part of the

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EXHIBIT D

Chemic Laboratories, Inc.
480 Neponset Street - Bldg. 7, Canton, MA 02021
Phone #: (781) 821-5600 facsimile #: (781) 821-5651

November 5, 2008

Anand K. Parekh, MD MPH
Office of Public Health & Science
U.S. Department of Health & Human Services
Anand.Parekh@hhs.gov

Dear Dr Parekh:

As per your request of June 18th please find the following response via email. Chemic Laboratories appreciates the reviewers' time and consideration surrounding the provided protocol. In order to provide clarification each point of interest has been specifically reviewed and detailed responses provided. Following your review of the provided responses please do not hesitate to contact me with any further questions or comments. Chemic Laboratories looks forward to your favorable responses.

Best regards,

Joseph St.Laurent
President, CSO

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November 5, 2008

1. THCA: the definition of THCA is not clear. Do the authors refer to the precursor to THC in plants that produce THC upon heating, or to 11-nor-Δ9-9-carboxy-THC, the metabolic product of THC? The author's state that the concentration of this compound will be determined, but the source of THCA is not provided and no further information on its detection, quantification, or results are provided? In addition, the physiochemical characteristics of this compound are quite different from the other cannabinoids and an appropriate internal standard should be included for quantification. It is quite possible that THCA in Cannabis Sativa products could differentially contribute to the amount of measurable THC in the three methods of analysis- Soxhlet extraction, vaporization and combustion. It is not known whether the THCA will decarboxylate at vaporization temperatures or whether it might decarboxylate during Soxhlet extraction (doubtful). This could introduce variability into the results. Has the THCA content been determined prior to testing? In general, NIDA does determine the THCA content of its cannabis' batches. This assumes THCA refers to the precursor acids.

THCA in the presented protocol refers to 11-nor-Δ9-9-carboxy-THC. The concentration will be determined by external standardization using a reference standard obtained from commercial sources (as applicable).

It is anticipated that the decarboxilation will occur during combustion and not using the various extraction procedures. It is the difference in isolation techniques that the authors are interested in.

2. Why would external standardization be necessary? Internal standardization is the preferred method of analysis. Would it not be feasible to fortify the Cannabis sativa plant material with internal standard rather than fortifying the methanolic solutions to account for losses during heating, absorption on the volcano parts or during combustion? Why is only one deuterated cannabinoid used as an internal standard? The committee believes that deuterated CBD and perhaps deuterated CBN may be available to improve quantification of these analytes.

It has been determined in previous studies that external standardization provides the necessary precision and accuracy to accurately determine the concentration of the cannabinoids isolated during the extraction and vaporization process. Although the CBD and CBN deuterated standards may be available, it has been determined in previous experimental investigations that the instrumental parameters described in the presented protocol support the relative response factors of the three analytes (i.e., CBD, CBN and THC) being equivalent, and therefore can estimate that the relative response factors of the deuterated analogs would be equivalent also.

3. Why is LCMS rather than LCMSMS utilized for identification of the cannabinoids? Why is only TIC used rather than single ion monitoring? How many ions are monitored for each cannabinoid (minimum three with two ion ratios gold standard analysis) and two minimum for each internal standard (one ion ratio)? Please submit the method validation criteria for the LCMS method showing sensitivity, specificity, accuracy or bias, imprecision, matrix effect evaluation, recovery (if performed), interferences, linearity, carryover evaluation and/or other criteria.

LC-DAD-MS is being used as the technique has been qualified in previous experiments to provide the necessary measure of precision and accuracy. DAD is being used for quantitation while TIC-MS is being used for identification. At a minimum three to five ions are used for identification and confirmation

4. What is known about pyrolytic conversion of the target cannabinoids by the volcano vaporizer and the combustion method?

Currently it has been determined that limited pyrolitic conversion occurs at the temperature prescribed within the protocol provided.

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November 5, 2008

5. Page 4 Tetrahydrocannabinol, cannabinol, cannabidiol and Tetrahydrocannabinol-acid are misspelled.

The finalized protocol will be amended to accommodate any misspelling.

6. Throughout the protocol data are used in the singular, data are always plural.

The finalized protocol will be amended to accommodate any grammatical issues. Please note where ever the term "Data" is used it is meant to indicate multiple sets of information. In the event a single informational point of interest is being made reference to the term "Datum" is used.

7. P 7 Why is the weight of the glass filter included in the total weight of the marijuana? Has potential absorption of cannabinoids to the balloon, reservoir or other parts of the volcano been determined?

Total lose of cannabinoids have been determined to be minimum in all the components with the exception of the glass fiber filter. It is for this reason that the tare and gross weight data are collected for all the samples tested.

8. P10 Acetonitrile is misspelled.

See comment #5

9. P10 evaluation criteria are inadequate.

Please note that all evaluation criteria established are in line with USP Category II validations and ICH criteria.

a. What are retention time criteria?

RT criteria is typically +/- 5%

b. What are appropriate chromatography criteria including peak shape, peak resolution, S/N?

Again USP criteria establishes peak resolution as > 2 and N/N >1:10 with >95%recovery

c. What criteria are in place for variability between the four calibrator injections within a single run?

Again variability in measured according to USP and ICH criteria. Variability between the analytes and multiple injections has been established as <5%

d. How many samples are included in each batch with the four calibration curves?

It is typical to include between 15 and 20 samples prior to assaying continuing calibration standard.

e. Are the concentrations of each calibrator individually determined against the entire curve?

Absolutely, as well as an acceptance criteria has been established in line with USP and ICH criteria.

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f. What is the acceptable concentration range? Are there procedures for eliminating specific calibrators if they do not meet the criteria?

Although it is not anticipated that calibrators will be dropped using statistical criteria such as Chauvenets criteria can allow for the removal of test standards. How many calibrators can be dropped from the curve? This has not been established at this time

g. Is there drift across a single batch with such a long run time (60 min)? Are calibrators prepared at the same time as samples?

Again continuing calibration accommodates any drift.

h. Where are quality control samples? Are quality controls (preferably 3 across the linear dynamic range of the curve) prepared independently and assessed at the beginning and end of the batch or more frequently?

Yes, QC samples are prepared at each of three concentrations and assayed across the samples set.

i. How were matrix effects evaluated? How were other endogenous compounds within the Cannabis sativa evaluated to assure lack of interference? Especially from other natural cannabinoids? Were cannabigerol, cannabichromene for example, evaluated for interference with target compounds?

All compounds are assayed with suitable resolution using HPLC-DAD-MS ensured quantitation and identity (i.e., specificity)

j. Although the compounds of interest appear to be present at concentrations well above the lower limit of linearity, what was the limit of quantification? Or was the lowest calibrator used for this purpose?

At this time the lower concentration from the standard curve is empirically determined as the limit of quantitation.

10. P11 Reference for Marijuana and Medicine was not included.

11. Was the valve, mouthpiece and/or filling chamber changed between samples? Is it changed routinely between subjects?

The valve and mouthpiece and filling chamber is not anticipated to be changed between test samples.

12. P 25. The common oven bag that is referenced is used for what application? Moisture content only or for delivery of cannabinoids.

The plastic oven bag is the means of collection of the vaporized THC and other cannabinoids

13. Why are no data presented for THCA with the other analytes?

THCA was added at the request of a previous reviewer; data is not available at this time

14. P32 the protocol indicates that all peaks with an area greater than the lowest calibrator area will be quantified, but it appears that uncalibrated peaks are not collected according to the instrument set up? Also, why is the origin included in the linearity? It is a bad practice to force the calibration line through the origin. However, the data did not appear to go through zero? What was done and what is the justification for this choice?

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The reviewer is correct all values greater than the lowest calibrator will be quantitated, as well as uncalibrated peaks will be collected for further evaluation at a future date. The origin is not being forced although the data at the null concentration is collected and placed into the curve to ensure any negative bias will be recognized during testing.

15. What is the internal standard for the PNA analysis? Was internal or external standardization used? Why not internal standardization if it was not the method used?

External standardization is being used however deuterated PNA standards are utilized as well.

16. P 40 Why was the Fragmentor ramp disabled? Why were multiple ions not monitored and ion ratios determined to specifically identify compounds?

It was determined in earlier experiments that that the analytes ionize with relatively equivalent fragmentation.

EXHIBIT E

Statement Of Frederic M. Scherer

in re Professor Lyle Craker
Drug Enforcement Administration Docket No. 05-16
January 30, 2009

1. I have been asked by representatives of Professor Craker to submit this analysis in connection with the Docket 05-16 proceedings before the Drug Enforcement Administration (DEA). I do so pro bono publico. I am professor emeritus at the John F. Kennedy School of Government, Harvard University, ~~and visiting professor at Haverford College, teaching a course on the economics of industry~~. Copies of my short-form biography and a list of my testimony in judicial and regulatory proceedings are attached as Appendices A and B.

2. The issue, as I understand it, is fourfold. First, DEA has the legal authority to designate production sources for the lawful production of such controlled substances as marijuana and is mandated under by 21 U.S.C. 823(a)(1) to "limit the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of those substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." Second, I understand that DEA has licensed a single source, Professor El Sohly at the University of Mississippi, to produce marijuana under contract to the National Institute on Drug Abuse (NIDA), the output of which is allocated by NIDA. Third, DEA has recently licensed Professor El Sohly to grow marijuana for lawful commercial purposes under contract to private industry. Fourth, I understand that Dr. Craker is seeking authorization to establish an alternative competitive source at the University of Massachusetts, whose output is to be used solely for lawful experimental purposes. That application has been denied, but is under review by the DEA in this proceeding.

3. I have been asked to address a statement contained in the DEA Final Order in this matter, published January 14, 2009 in the Federal Register at 74 FR 2101; specifically, at 74 FR 2131, footnote 11, the quoted portion of a 2004 letter from Assistant Attorney General William Moschella to Congressman Souder. The quoted portion of the letter provides as an example of "inadequate competition among the existing manufacturers of the particular controlled substance that the appellant seeks to produce" the following: "substantial overcharging by the existing manufacturers of that controlled substance."

4. In my professional opinion, another more glaring example of inadequate competition is a system in which a monopolist refuses to sell, at any price, to certain buyers.

5. My understanding is that, in addition to providing only marijuana of relatively low potency, NIDA has in the past denied applications for marijuana supplies to be used solely for legitimate research. For those applications, the supply is constrained to zero. When there is a market demand for a commodity and there is no supply, any reputable economist would agree that the true price is the so-called shadow price, also called the implicit price, that is, the price consistent with finite demand but zero supply. Under the circumstances here, the shadow price is infinity for certain demand functions, i.e., those derived from Cobb-Douglas utility functions (Paul Douglas was a U.S. senator in the 1950s), or in other special cases, the price just above the price at which the demander's demand is choked off to a quantity of zero. In either case, such a shadow price is higher, usually much higher, than the price at which a monopoly would maximize its profits. And the monopoly price is higher than a competitive price. Thus, when a monopoly supplier denies supplies to legitimate demanders, there is a very significant impairment of competition – more significant than if the supplier merely levied a monopoly price.

6. Scholars of all ideological shades who accept the basic premises favoring a market economy agree that refusal to supply by an entity with monopoly power is at least as undesirable as supplying at a monopoly price. As Friedrich A. Hayek observed in his book, The Road to Serfdom (1976 University of Chicago revised edition, p. 93):

Our freedom of choice in a competitive society rests on the fact that, if one person refuses to satisfy our wishes, we can turn to another. But if we face a monopolist we are at his mercy. And an authority directing the whole economic system would be the most powerful monopolist conceivable. While we need probably not be afraid that such an authority would exploit this power in the manner in which a private monopolist would do so, while its purpose would presumably not be the extortion of maximum financial gain, it would have complete power to decide what we are to be given and on what terms... The power conferred by the control of production and prices is almost unlimited.

Professor Hayek's book is considered the bedrock of contemporary conservative economics. And I hardly need to say that Hayek abhorred the kind of power he was describing. On the more liberal side (by a modern, not 19th Century, definition of the term), consider the 1959 treatise by Carl Kaysen and Donald F. Turner, Antitrust Policy: An Economic and Legal Analysis, p. 14:

The demand for limiting business power springs more often from those who feel themselves at a disadvantage in interbusiness transactions than it does from households ... Competition in this context is desirable because it substitutes an impersonal market control for the personal control of powerful business executives, or for the personal control of government bureaucrats. The impersonality of market regulation makes it fair in the eyes of those subject to it; the sense

of fairness is greater when the same restriction on conduct is imposed by the market than when it is viewed as the result of a personal decision by a powerful individual.

Shortly after publishing the book, Kayson became an economic adviser to President Kennedy; Turner was Assistant Attorney General for Antitrust during the Johnson Administration.

7. In declaring under 21 U.S.C. 823(a) that controlled substances should be supplied under "adequate competitive conditions" for lawful purposes, the U.S. Congress was following a four-century legal tradition. The seminal case is Darcy v. Allein, 1603, which is reprinted in my compendium, Monopoly and Competition Policy, vol. I, pp. 6-11. It condemned as contrary to the common law a grant by Queen Elizabeth I of a monopoly over the supply of playing cards in England. That and other High Court decisions led the Parliament in 1623 to pass the Statute of Monopolies, which singled out patents and copyrights as the sole allowable monopoly grants government could make under English law. That policy was implicitly endorsed by the U.S. Founding Fathers when they authorized Congress in Article I, Section 8, of the Constitution to grant for limited times the exclusive right to authors and inventors in their writings and discoveries, but articulated expressly no other situations in which the government was to confer exclusive rights.

8. It is my understanding that no exclusive patent rights limit the supply of marijuana to lawful scientific users. Even for the principal type of monopoly grant sanctioned in the U.S. Constitution, Congress declared an explicit exemption in the Hatch-Waxman Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417). The so-called Bolar amendment exempts would-be generic suppliers of a drug from the exclusive rights of drug product patent holders for the purpose of carrying out clinical trials in advance of patent expiration so that their generic products can be ready for marketing at the time valid patents expire.

9. A considerable part of my professional career has been devoted to studying the relationships between market structure and technological progress. One of my most important findings has been that innovation, quality, and diversity of product characteristics satisfying consumers' demands are more likely to be achieved when there are multiple producers than when there is only one, i.e., a monopoly. For a summary, see F. M. Scherer and David Ross, Industrial Market Structure and Economic Performance (3rd edition: 1990), pp. 600-607 and 639-660.

10. To conclude, I believe DEA is quite wrong in concluding that there is no impairment of competition when legitimate supplies of marijuana are sold at cost to authorized customers. Competitive problems emerge when costs are higher than those of alternative sources, or when supplies are denied -- i.e., the quantity supplied is zero -- to other would-be buyers who meet the scientific and/or medical criteria of the Food and Drug Administration (FDA) or, in the case of laboratory research, have the necessary DEA licenses. Denial of a license to the University of Massachusetts to produce marijuana for lawful scientific and medical purposes is contrary to both the spirit of 21 U.S.C. 823(a)(1) and to sound public policy.

11. I swear that the statements in para. 1-10 above are true to the best of my knowledge.

Frederic M. Scherer

Frederic M. Scherer

March 11, 2009

BIOGRAPHY OF F. M. SCHERER

F. M. Scherer is Aetna Professor Emeritus at the John F. Kennedy School of Government, Harvard University. He has also taught at Princeton University, the University of Michigan, Northwestern University, Swarthmore College, Haverford College, the Central European University, and the University of Bayreuth. In 1974-76, he was chief economist at the Federal Trade Commission. His undergraduate degree was from the University of Michigan; he received his M.B.A. and Ph.D. from Harvard University. His research specialties are industrial economics and the economics of technological change, leading inter alia to books on *Industrial Market Structure and Economic Performance* (third edition with David Ross); *The Economics of Multi-Plant Operation: An International Comparisons Study* (with three co-authors); *International High-Technology Competition*; *Competition Policies for an Integrated World Economy*; *Mergers, Sell-offs, and Economic Efficiency* (with David J. Ravenscraft); *Innovation and Growth: Schumpeterian Perspectives*; *The Weapons Acquisition Process* (two volumes, one with M. J. Peck); *Industry Structure, Strategy, and Public Policy*; *New Perspectives on Economic Growth and Technological Innovation*, and most recently, *Quarter Notes and Bank Notes: The Economics of Music Composition in the 18th and 19th Centuries*. His personal web page is found at the Kennedy School of Government faculty profiles site.

LEGAL PROCEEDINGS IN WHICH F. M. SCHERER HAS SUBMITTED EVIDENCE

Testimony in pre-injunction hearing, U. S. v. G. Heileman et al., U.S. Federal District Court for the Eastern District of Michigan (1972). Subject: market definition, economics of the brewing industry. Pro bono on behalf of Heileman et al.

Deposition and testimony in U.S. v. International Business Machines Corp., U.S. Federal District Court for the Southern District of New York (1975). Subject: principles of industrial organization analysis, market definition, behavior of dominant enterprises. Pro bono on behalf of Department of Justice.

Deposition and testimony in re Kellogg Co. et al., Docket 8883, Federal Trade Commission, 1977. Subject: market structure in the cereal industry, pricing and other behavior, performance, and proposed remedies. On behalf of Federal Trade Commission.

Testimony in the matter of AC Polyphase Electric Motors, International Trade Commission, 1980. Subject: economics of large electric motor industry, effects of alleged dumping. On behalf of Fujitsu.

Deposition and testimony in Marathon Oil Co. v. Mobil Oil Corp., U.S. Federal District Court for the Northern District of Ohio, 1981. Subject: market definition, impact of proposed merger on competition in gasoline marketing. On behalf of Marathon.

Affidavit in Irwin L. Jacobs et al. vs. G. Heileman Brewing Co. et al., U.S. Federal District Court for the District of Delaware, 1982. Subject: mergers and competition in the brewing industry. On behalf of Pabst/Heileman.

Affidavit in re Industrial Gas Antitrust Litigation, 80 C 3479, U.S. Federal District Court for the Northern District of Illinois, April 1982. Subject: pricing of commodities with high outbound transportation costs. On behalf of defendants.

Testimony before an arbitration panel in the matter of Stauffer Chemical Company v. PPG Industries under the FIFRA Act, 1983. Subject: economics of the herbicide industry, principles for determining compensation for use of EPA registration data. On behalf of PPG Industries.

Memoranda and testimony before the International Trade Commission and the International Trade Administration, in the matter of Softwood Lumber Imports, 1983 and 1986. Subject: theory of rent and stumpage charge determination. On behalf of Canadian federal and provincial governments.

Affidavit in Schmidt/Stroh v. Heileman/Pabst, U.S. Federal District Court for the Eastern District of Michigan, 1984. Subject: mergers and competition in the brewing industry. On behalf of Heileman/Pabst.

Deposition in Northrop Corp. v. McDonnell Douglas Corp., 1984. Subject: joint ventures, monopolization, and market definition. On behalf of McDonnell Douglas.

Deposition, memoranda, and testimony in U.S. v. Archer-Daniels-Midland Co. et al., U.S. Federal District Court for Iowa, 1989. Subject: market definition, merger efficiencies defense. On behalf of Archer-Daniels-Midland.

Deposition in Comm-Tract Corp. v. Northern Telecom Inc., U.S. Federal District Court for Massachusetts, 1991. Subject: alleged tying. On behalf of Northern Telecom.

Declarations in Mahurkar Double Lumen Hemodyalysis Catheter Patent Litigation, MDL-853, U.S. Federal District Court for the Northern District of Illinois, 1992-93. Subject: patent infringement damages estimation. On behalf of Impra Inc.

Testimony in re Intel Corporation before the Taiwan Fair Trade Commission, March 31, 1994. Subject: exclusionary patent litigation and product allocations. On behalf of Advanced Micro Devices Inc.

Declaration and testimony in Eli Lilly & Co. v. American Cyanamid et al., U.S. Federal District Court for the Southern District of Indiana, 1995. Subject: economics of generic drug competition, acquisition of patents. On behalf of American Cyanamid.

Expert report and deposition in Potash Antitrust Litigation, MDL 981, U.S. Federal District Court, Minnesota, 1995. Subject: alleged price conspiracy, unique aspects of Kalium Canada operations. On behalf of Vigoro Corporation.

Deposition, expert report, and testimony in re Toys "R" Us, Docket No. 9278, Federal Trade Commission, 1997. Subject: alleged boycott of competitive distribution channels. On behalf of the Federal Trade Commission staff.

Expert report in Key Pharmaceuticals Inc. v. ESI-Lederle, U.S. Federal District Court, Eastern District of Pennsylvania, 1997. Subject: alleged patent infringement and damages. On behalf of ESI-Lederle.

Expert report in Branded Drug Litigation, 1996, on behalf of Pfizer Inc. Subject: alleged collusion not to offer discriminatory price concessions to retail pharmacists.

Expert reports and deposition in re Intel Corporation, Docket No. 9288, Federal Trade Commission, 1998. Subject: Denial of technical information in intellectual property disputes. On behalf of Federal Trade Commission Staff.

Expert report in Multivideo Labs, Inc., v. Intel Corporation, 1999. Subject: Consequences of technological standard non-compliance notification. On behalf of Multivideo Labs.

Two expert reports submitted to Federal Energy Regulatory Commission in re Five Year Review of Oil Pipeline Index, 2000. Subject: Price cap indexing of petroleum pipeline rates. On behalf of several independent pipeline shippers.

Expert report on behalf of Amgen, Inc., in an Arbitration between Amgen and Ortho Division of Johnson & Johnson, 2001. Subject: Impact of J&J competition on prices charged for Erythropoietin.

Declaration relating to a Chase Transportation Co. Petroleum Product tariff filing with the Federal Energy Regulatory Commission, 2003, on behalf of Sinclair Oil. Subject: impact of annual tendering volume requirements on competition.

Expert report in Super-Valu Inc. v. Rainbow Food Group, Minnesota State Court, 2003, on behalf of Super-Valu. Subject: laying out the bounds for a defense of monopolization charges.

Expert report in Eli Lilly & Co. v. Apotex Inc., Federal Court of Canada, 2003, on behalf of Apotex. Subject: patent infringement and collusive patent acquisition.

Expert report and testimony in Commission of the European Communities v. Microsoft, 2004, on behalf of intervenor Real Networks Inc. Subject: Microsoft's bundling of multimedia players and the probability of market "tipping."

Expert report in Ross et al. v. American Express Company et al., U.S. District Court for the Southern District of New York, on behalf of American Express. Subject: alleged collusion in setting of foreign currency conversion charges.

Other:

Memorandum to Attorney General Griffin Bell on the merger

between LTV - Jones & Laughlin and Lykes - Youngstown, June 1978. Subject: market structure, pricing, efficiencies, and employment impacts. Pro bono on behalf of Antitrust Division.

Two memoranda as advisor to Judges Robson and Will in MDL-250 (the folding carton litigation), U.S. Federal District Court for the Northern District of Illinois, 1979-1981. Subject: impact of conspiracy on prices.

Memoranda as advisor to Judge Will in MDL 89 C 5251 (glass containers litigation), Federal District Court for the Northern District of Illinois, 1991. Subject: existence and effects of alleged price-fixing conspiracy.

Amicus curiae brief (with Robert Litan et al.) on alternative remedies in U.S. v. Microsoft, April 27, 2000.

Amicus curiae brief (with Parker C. Folse and Justin A. Nelson) submitted to the U.S. Supreme Court, in Illinois Tool Works et al. v. Independent Ink Inc., September 2005. Subject: presumptions in patent-based tying cases.

Amicus curiae brief (with William S. Comanor) submitted to the Supreme Court, in Leegin Creative Leather Products v. PSKS Inc. (November 2006). Subject: per se treatment of vertical price restraints.

EXHIBIT F

FDA Safety Page

Drug errors associated with opium tincture and paregoric

Since 1997, the Food & Drug Administration has received eight cases of medication errors involving opium tincture and paregoric. Among the six cases in which a product was administered, three resulted in fatal outcomes, one required treatment at an emergency room, one required prolonged treatment in a hospital, and one involved an unknown outcome.

In six of the eight cases, the wrong drug product (n=3), drug concentration (n=2), or dose/drug volume (n=1) was given to the patient. In the other two cases, the medication was either not administered or it could not be determined whether the medication was administered. The medication errors involved adults (n=3), infants less than one year of age (n=3), or an age was not reported (n=2).

An initial analysis of the medication errors indicates several factors have contributed to the errors. One contributing factor to medication errors is that over the years additional names have been associated with the two products, and these additional names are listed below:

Opium tincture, USP:
Opium tincture, deodorized
Opium tincture (laudanum)
Deodorized tincture of opium
Opium
Tincture of opium
DTO

Paregoric, USP:
Tincture of opium, camphorated
Tincture of paregoric

Also, some healthcare practitioners have mistakenly used the abbreviation "DTO" to indicate diluted tincture of opium. However, the letters *DTO* are actually an abbreviation for deodorized tincture of opium.

In 2001, the agency received a report in which the abbreviation DTO caused confusion. A 13-day-old infant was transferred from an obstetrics hospital with a diagnosis of opiate withdrawal. A transfer order was written as "DTO 0.7 mL PO q4h." The pharmacist processing the order identified the abbreviation DTO to represent deodorized tincture of opium. When the pharmacist attempted to verify the dose with common reference sources, he determined the dose to be excessive. The pharmacist contacted the obstetrics hospital pharmacy personnel to clarify the transfer order and discovered the abbreviation DTO was meant to indicate a 25-fold dilution of deodorized tincture of opium. If deodorized tincture of opium had been dispensed, then the infant would have received a 42-mg daily dose, instead of the prescribed 1.68-mg daily dose. Vigilance by the pharmacist prevented an abbreviation error from causing patient harm. It is important to remember there is no abbreviation for *diluted tincture of opium*, and all medication abbreviations should be avoided when prescribing.

The presentation of the product strength on the container label and package insert is another source of confusion. The presentation does not easily allow the reader to determine opium tincture is *25 times more concentrated* than paregoric. This 25-fold concentration difference is the reason opium tincture is dosed in drops (or a fraction of a milliliter) and paregoric is dosed as 5-10 milliliters (or one to two teaspoonfuls). There is no pediatric dosing guideline for opium tincture because of the high morphine concentration. However, paregoric can be used to treat diarrhea in children at a dose of 0.25-0.5 ml/kg one to four times a day.

Another contributing factor to the medication errors is the overlapping indications, which do not aid in differentiating the products. Both products are indicated for the treatment of diarrhea. Reference sources also indicate both products can treat the same unlabeled indications of use, which include the relief of pain, neonatal abstinence syndrome, and the management of short bowel syndrome.

Three cases of medication errors involving adult patients, as well as one case involving a patient of unknown age, and three additional cases involving infants are summarized in the table on the right. All four cases involving adults were errors that resulted in the administration of the wrong product, three of which contributed to the death of the patient. The three additional cases involving infants were errors that resulted in the administration of the wrong dose or concentration.

These medication-error reports indicate the risk for patient harm and injury is increased if opium tincture is dispensed or administered in error. This would be expected since opium tincture is 25-fold more concentrated than paregoric.

The FDA will be working with the manufacturers on container label and package insert labeling revisions. However, in the interest of minimizing potential user error and maximizing patient safety, we recommend increasing your staff's awareness of the confusion between these products.

By
Scott Dallas, Carol Holquist, and Jerry Phillips

MEDWATCH

Scott Dallas, R.Ph., is a Safety Evaluator; Carol Holquist, R.Ph., is the Deputy Director of the Division of Medication Errors and Technical Support; and Jerry Phillips, R.Ph., is the Associate Director for Medication Error Prevention, Office of Drug Safety at the Food & Drug Administration.

To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.

Med-error reports associated with opium tincture and paregoric

Patient age and date received	Abbreviated narrative of cases involving adults
Unknown 5/97	A patient was ordered 8 mL of Paregoric every eight hours to be added to a tube feeding bag. A recent graduate pharmacist did not realize that Paregoric and Deodorized Tincture of Opium were not the same drug. The container was labeled "Deodorized Tincture of Opium (Paregoric) 1 g/100 mL." The reporter stated the patient received an extra 120 mg of morphine. The outcome was unknown.
91 years old 6/00	The patient was given a dose of 10 mL of Opium Tincture (deodorized) in a nursing home. Patient passed away shortly after the dose administration. The dose prescribed was "5-10 mL by mouth every 6 hours as needed." The nursing home pharmacy printer would "print the highest dose on the prescription label and therefore it gave a dose of 10 mL." A prescription was faxed to the pharmacy department at the nursing home but was not verified by the pharmacy department.
51 years old 4/02	The patient was prescribed camphorated Tincture of Opium to treat chronic diarrhea. The pharmacy dispensed Opium Tincture, which contains 25 times the amount of Morphine as Paregoric. After taking the Opium Tincture in the morning, the patient became weak and complained of feeling tired and achy. Later the patient was found unresponsive and could not be revived. The medical examiner's office found that the patient's death was caused by morphine intoxication.
85 years old 5/03	A patient was prescribed Opium Tincture camphorated, 5 mL p.o. b.i.d./t.i.d. 2-3x/day until diarrhea stops. That evening, the patient just lay in bed with difficulty breathing. He could not talk or even open his eyes. Three days later, the patient passed away. The foster care had all of the prescriptions delivered from a community pharmacy. A family member learned that evening pharmacy personnel came back with a new bottle of Opium and took the original bottle. The new bottle was labeled Opium 10% Tincture 0.6 mL 2-3 times a day until diarrhea stops.

Patient age and date received	Abbreviated narrative of cases involving infants
9 months 1/1996	A prescription for Paregoric was written for 10-15 drops every 4-6 hours for pain. The prescription label was dispensed as 10-15 cc per dose. The mother called the physician to verify the dose before the medication was administered to the infant.
Newborn 1/02	A full-term baby was to go through a weaning process from opiate dependency over 21 days. However, on the 19th or 20th day of therapy, it was discovered a wrong concentration was prepared. The physician ordered 0.35 mL q4h of a 0.4 mg/mL solution. However, the baby received a 0.35 mL q4h of a 10 mg/mL solution. The baby required an additional 3 months of weaning.
One month 3/03 & 4/03	An outpatient pharmacy dispensed Opium Tincture, USP to the infant. The report stated the pharmacist was unfamiliar with the concentration and failed to dilute the product properly. The report indicated the infant was treated in the emergency room and required patient monitoring.

EXHIBIT G

Drug Information Online
Drugs.com

Opium Tincture / Paregoric

Pronunciation: (OH-pee-uhm/par-eh-GORE-ik)
Class: Opioid analgesic

Trade Names:
Opium Tincture, Deodorized
- Liquid 10 mg anhydrous morphine equiv./mL

Trade Names:
Paregoric
- Liquid 2 mg anhydrous morphine equiv./5 mL

Pharmacology

Enhances tone in long segments of longitudinal muscle and inhibits propulsive contraction of both circular and longitudinal muscles.

Pharmacokinetics

Absorption

Morphine content well absorbed from GI tract.

Metabolism

Rapidly metabolized in the liver following oral administration. Morphine content undergoes conjugation with glucuronic acid.

Elimination

Approximately 75% is excreted in the urine within 48 h.

Indications and Usage

Treatment of diarrhea.

Contraindications

Children (opium tincture); diarrhea caused by poisoning until toxic material is eliminated from GI tract.

Dosage and Administration

Adults

PO Opium tincture : 0.6 mL 4 times daily. Paregoric : 1 to 2 teaspoonfuls (5 to 10 mL) 1 to 4 times/day.

Children

PO Paregoric : 0.25 to 0.5 mL per kg of body weight 1 to 4 times/day.

General Advice

- Use caution when selecting product. Do not confuse opium tincture with paregoric. Opium tincture contains 25 times more morphine than paregoric and if given in equivalent mL doses may result in a potentially fatal overdose.
- To reduce risk of dosing error, consider diluting opium tincture (10 mg morphine/mL) so that morphine concentration is equivalent to that in paregoric (0.4 mg morphine/mL).
- Administer without regard to meals. Administer with food if GI upset occurs.
- Measure and administer prescribed dose of opium tincture using dosing syringe.
- Measure and administer prescribed dose of paregoric or diluted opium tincture using dosing syringe, dosing spoon, or dosing cup.

Storage/Stability

Store opium tincture and paregoric at controlled room temperature (59° to 86°F). Protect paregoric from light and excessive heat.

Drug Interactions

Antihistamines, chloral hydrate, CNS depressants, glutethimide, methocarbamol, tricyclic antidepressants

Because of additive effects, dosage reduction may be indicated.

Cimetidine

Monitor for increased respiratory and CNS depression. Coadministration of cimetidine and morphine has been reported to cause apnea, confusion, and muscle twitching.

Laboratory Test Interactions

None well documented.

Adverse Reactions

Dermatologic

Pruritus; urticaria.

GI

Constipation; nausea; vomiting.

Precautions

Pregnancy

Category C .

Lactation

Use with caution.

Children

Opium tincture is contraindicated.

Special Risk Patients

Use with caution in the elderly, in debilitated individuals, and in patients with increased intracranial pressure, cerebral arteriosclerosis, hepatic cirrhosis or liver insufficiency, GI hemorrhage, myxedema, emphysema, and bronchial asthma.

Drug dependence

Has abuse potential; addiction may result.

Overdosage

Symptoms

Nausea, vomiting, miosis, cool and clammy skin, respiratory and CNS depression, bradycardia, hypotension, skeletal muscle flaccidity, noncardiogenic pulmonary edema, hypoglycemia, apnea, circulatory collapse, cardiac arrest, death.

Patient Information

- Advise patient medication may be habit forming and to take as prescribed and not to increase the dose or frequency of use unless advised by health care provider.
- Advise patient or caregiver to take, or administer, prescribed dose up to 4 times daily as needed to control diarrhea.
- Advise patient or caregiver to take, or administer, each dose without regard to meals but to take, or administer, with meals if stomach upset occurs.
- Advise patient or caregiver using paregoric to measure and administer prescribed dose using dosing syringe, dosing spoon, or dosing cup.
- Advise patient using opium tincture to measure and administer prescribed dose using dosing syringe.
- Advise patient if a dose is missed to skip that dose and take the next dose at the regularly scheduled time. Caution patient not to double the dose to catch up.
- Advise patient if diarrhea is not controlled, not to increase the dose or frequency of administration of medication but to inform health care provider.
- Advise patient to discontinue therapy when diarrhea resolves. Caution patient that continued use may cause severe constipation.
- Caution patient to avoid alcohol and other CNS depressants while using this medication.
- Caution patient drug may cause drowsiness and to use caution while driving or performing other tasks requiring mental alertness or coordination until tolerance is determined.

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EXHIBIT H

close window

MedicineNet.com
We Bring Doctors' Knowledge to You

Source: http://www.medicinenet.com

GENERIC NAME: TINCTURE OF OPIUM - ORAL LIQUID (TINK-chure of OH-pee-um)

Medication Uses | How To Use | Side Effects | Precautions | Drug Interactions | Overdose | Notes | Missed Dose | Storage

USES: Opium is a narcotic used to treat diarrhea or pain.

HOW TO USE: Take this medication by mouth as directed. May take with food or meals if stomach upset occurs. Carefully measure each dose using the dropper provided. The drops may be mixed with soft food, water or juice. Use this medication exactly as directed by your doctor. Do not increase your dose, use it more frequently or use it for a longer period of time than prescribed because this drug can be habit- forming. Also, if used for an extended period, do not suddenly stop using this drug without your doctor's approval. Over time, this drug may not work as well. Consult your doctor if this medication stops working well.

SIDE EFFECTS: Lightheadedness, dizziness, drowsiness, nausea, vomiting, blurred vision may occur. If any of these effects continue or become bothersome, inform your doctor. Notify your doctor if you develop: tremor, mood/mental changes, rapid heart rate. In the unlikely event you have a serious allergic reaction to this drug, seek immediate medical attention. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Tell your doctor if you have: liver disease, heart disease, gallbladder problems, intestinal diseases, an enlarged prostate, asthma or other breathing problems, seizures, drug dependency, drug allergies. Use caution driving or operating machinery or doing activities requiring alertness. Rise slowly from a lying or sitting position to lessen the occurrence of dizziness, lightheadedness or fainting. This medication should be used only if clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known if this drug is excreted into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Tell your doctor of any over-the-counter or prescription medication you may use, including: other narcotic pain relievers, sedatives, cimetidine. Avoid using alcohol while taking this medication as dizziness and drowsiness effects will increase. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include trouble breathing, severe drowsiness, unconsciousness, severe dizziness; cold or clammy skin; or irregular heartbeat.

NOTES: This medication must be used only by the person for whom it was prescribed. Do not allow anyone else to take this medication.

MISSED DOSE: If you miss a dose, take it as soon as remembered; do not take it if it is near the time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE: Store at room temperature between 59 and 86 degrees F (15 and 30 degrees C) away from heat, light and moisture. Do not store in the bathroom. Keep this and all medications out of the reach of children.

Last Editorial Review: 3/2/2005

Report Problems to the Food and Drug Administration

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit the FDA MedWatch website or call 1-800-FDA-1088.