

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.

2. I have been asked to address the testimony on August 25, 2005, of Mr. Matt Strait of DEA. Mr. Strait testified as the coordinator of the DEA response to Dr. Craker's application for a license. As coordinator, he testified he did not examine the issue of competition because he saw no issue of competition in the provision of marijuana. Mr. Strait noted that because the DEA-licensed University of Mississippi source "provides marijuana to researchers at a not for profit basis," there was no issue of competition to be considered. In other words, because supplies are provided at cost, there is no lack of competition.

3. My interpretation of his rather imprecise testimony is that, since the University of Mississippi source prices its supplies of marijuana at cost rather than above cost, there is no monopoly problem; the requisites of competition are satisfied.

4. My understanding is that, in addition to providing only marijuana of relatively low potency, NIDA has in the past denied some applications for marijuana supplies to be used in FDA-approved research studies. 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, Kaysen 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, it is quite wrong to say 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. Granting a license to the University of Massachusetts to produce marijuana for lawful scientific and medical purposes would improve competitive conditions for the market for marijuana for legitimate medical and research purposes.

MOTION SEEKING LEAVE TO FILE

FOURTH SUPPLEMENTAL PREHEARING STATEMENT

Respondent seeks leave to file the above Fourth Supplemental Prehearing Statement for the following reasons: The material is not voluminous. Further, it is necessary testimony to rebut the testimony of DEA witness Matthew Strait, who, as coordinator of the response to the Craker application, testified that he did not investigate the statutory factor of competition because there was no issue of competition. Thus, the need for this testimony and exhibit did not arise until he testified during the hearing, and could not have been submitted before the hearing.

In the alternative, if this testimony and exhibit are not accepted as rebuttal evidence, Respondent respectfully moves to re-open its case for the limited purpose of introducing expert testimony demonstrating that the effect of allowing Dr. Craker to be licensed as an additional source of medical marijuana to be used for medical research purposes will have the effect of increasing competition, since it will mean that the number of suppliers changes from one to two. Respondents had intended to introduce evidence about the effect of adding an additional supplier to the existing field of one through the testimony of Dr. Craker and Dr. Doblin, believing that

such testimony would be within the knowledge of participants in that market, but the Court precluded their testimony on that point because neither is an expert in economics. Thus, respondent now offers such expert testimony to allow the Court to fully consider the required statutory factor relating to "adequately competitive conditions." Because this notice is filed more than five weeks before the next hearing date, the government will not be prejudiced by this limited request to re-open, and the government should have adequate time to find a rebuttal witness, if necessary.

Respondent will fax this Fourth Supplemental Prehearing Statement to opposing counsel.

Respectfully submitted,

LYLE E. CRAKER, Ph.D.

By his counsel,
Julie M. Carpenter
Jemer & Block, LLP
601 13th Street, N.W.
Washington, DC 20005

Dated: November 3, 2005

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2005, I caused a copy of the foregoing Respondent's Fourth Supplemental Prehearing Statement and Motion for Leave to File It to be served on the following by facsimile transmission:

Brian Bayly, Esq.
Office of the Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Washington, DC 20537

Julie M. Carpenter