

**UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

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| In the Matter of |) | |
| |) | |
| |) | Docket No. 05-16 |
| LYLE E. CRAKER, PH.D. |) | |
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**RESPONDENT’S FOURTH SUPPLEMENTAL PREHEARING STATEMENT AND
MOTION FOR LEAVE TO FILE IT**

Respondent respectfully submits the following Fourth Supplemental Prehearing Statement, and a motion for leave of court to file it, as follows:

RESPONDENT’S FOURTH SUPPLEMENTAL PREHEARING STATEMENT

Respondents will present the testimony of an expert in economics, Dr. Frederic M. Scherer, 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. Dr. Scherer’s CV will also be submitted as an additional exhibit, and a copy of that exhibit is attached hereto.

Dr. Scherer will testify as follows:

1. My testimony is based on the following assumptions: 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 these 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 medical experimental purposes.

2. I have been asked to address the testimony on August 25, 2005, of Mr. Matt Strait of DEA. Mr. Strait, the coordinator of gathering information for the DEA to respond to Dr. Craker's application, testified that when he coordinated that response, he did not examine the issue of competition because there was 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, since, according to Mr. Strait, the words used in the Code of Federal Regulations "all seem to be geared around the economics."

3. My interpretation of this 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 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, 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, I believe Mr. Strait is quite wrong in testifying 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.

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. Thus, the need for this testimony did not arise until he testified during the hearing, and could not have been submitted before the hearing.

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

Respectfully submitted,

LYLE E. CRAKER, Ph.D.

By his counsel,
Julie M. Carpenter
Jenner & Block, LLP
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Dated: November 2, 2005

CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2005, I caused a copy of the foregoing Respondent's Third Supplemental Prehearing Statement and Motion for Leave to File It to be served on the following by facsimile transmission:

Brian Bayly, Esq.
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Julie M. Carpenter