the medical profession—on which Upjohn sought to rely.

Because controlled studies did not become routine until a few years ago, most drug houses do not have, and have not subsequently obtained, this type of data to support older products. They were hoping that in evaluating a drug's efficacy, FDA would accept the more generalized historical evidence. FDA would not, and the court says it does not have to.

As a consequence of the court ruling, if FDA questions the efficacy of a marketed drug, the manufacturer must go out and produce the necessary data if it can.

FDA, at present, declines to say how it plans to implement the court decision, but when the last roadblock is knocked down, it is expected to act against some 90 combination antibiotics, as well as other drugs that the NAS review found to be deficient.

A spokesman for Upjohn says company lawyers have yet to decide what their next move will be. The appeals court gave the company until March 9 to seek a stay before the Supreme Court. □

POLLUTION STANDARDS

Planning Philadelphia's air

Air quality standards for the three-state Philadelphia Air Quality Control Region were approved March 2 by the Health, Education and Welfare Department's Air Pollution Control Administration, the first such regional approval under the 1967 amendments to the Clean Air Act.

The region—which includes parts of Pennsylvania, New Jersey and Delaware — must submit implementation plans, including emission standards and enforcement procedures, by May 11. The air quality standards define ambient air goals, but the emission standards will apply to actual emissions from industrial plants and other air polluters, and thus will be the means by which the region hopes to meet its goals.

Air quality standards—and the emission standards that will follow—apply to sulfur oxides and particulates, the only two pollutants for which HEW has issued criteria under the 1967 amendments. Although the three states have joined together in the Air Quality Region, the standards approved by HEW differ for each state. All fall within the HEW criteria calling for a maximum of 80 micrograms of particulates and 115 micrograms of sulfur oxides per cubic meter. Delaware's standards are the most stringent.

Reductions as high as 70 percent for sulfur oxides and 56 percent for particulates will be achieved if the goals are met. □

LUNAR QUARANTINE

A puzzle of toxicity

Scientists studying the samples of lunar soil returned from the moon by Apollo 11 and 12 are united in unambiguously emphasizing that they contain no evidence of life forms or precursors of life forms.

Yet a puzzle of another kind with implications for back contamination has arisen. Soil from Apollo 11 core tube samples has had a toxic effect on earth bacteria. This information, which Dr. Gerald Taylor, a scientist at the Manned Spacecraft Center, describes as preliminary, was known to members of the Lunar Quarantine Review Committee of the National Academy of Sciences' Space Science Board. It was one reason among several for a recommendation that full quarantine procedures be continued through the Apollo 13 flight in April.

After receiving the committee's report last weekend the National Aeronautics and Space Administration decided to abide by the recommendation. The NASA decision was announced formally in Washington Monday without reference to the toxicity evidence. The quarantine decision, says Chester M. Lee, Apollo 13 mission director, was "based solely upon the fact that a segment of the scientific community considers the hilly upland site to constitute a new lunar environment in comparison with Apollo 11 and 12."

The evidence of toxicity emerged when the NASA scientists in Houston subjected three types of bacteria to four types of lunar soil samples. The bacteria grew in three, but died when subjected to the fourth—the Apollo 11 core tube soil sample.

The bacteria chosen for the test represented a cross-section of terrestrial organisms: *Azotobacter vinelandii*, a common soil bacteria; *Staphylococcus aureus*, which caused a rash on the Apollo 12 crew, and *Pseudomonas aeruginosa*, a common laboratory bacteria.

The four soil types exposed consisted of two groups of randomly collected surface soil and two core tube samples, one from each mission.

The scientists have not determined what is responsible for the toxicity. They are repeating the experiments with fresh material from Apollo 11 and 12 core tube samples. "We are involved in a complicated process of extracting the soil in an attempt to isolate the toxic agent," says Dr. Taylor.

Since the source of the toxicity is still unknown, Dr. Taylor believes the decision to continue the quarantine for the next flight is a prudent and necessary precaution.

The decision conflicted with a recommendation in January by the Interagency Committee on Back Contamination (ICBC) to drop quarantine restrictions. Later in January, the planetary biology committee, a subcommittee of NASA's Space Science Applications Steering Committee, strongly opposed the ICBC recommendation. Dr. Richard S. Young, steering committee chairman, explained that in question were several "observed biological responses to lunar soil still unexplained.

"Although most likely these responses do not represent a terrible hazard to the earth," he said, his committee felt more investigation was needed.

"Although lunar geologists assure us that the Apollo 11 and 12 soil samples are representative of 95 percent of total lunar soil, that is not enough," says Dr. Young. "We can't be assured until the selenologists are 99.999 percent sure."

During Apollo 13 three 10-foot holes will be drilled into the lunar regolith at the Fra Mauro highland landing site. Two holes are for temperature probes to measure the flow of heat to the surface. The third is to obtain an eight-foot core sample. The Apollo 11 core tube sample was only one foot in depth, but the astronauts had difficulty driving the core tube into the regolith. The sample may have been the "native moon itself" rather than a mixture of native soil and meteoritic material, Dr. Taylor suggests.

Selenologists agree that the surface soil, sterilized by radiation and temperature changes, is devoid of life on the moon, although plants grown in moon soil flourished on earth. Dr. Taylor's question was whether deeper protected soil could support life. The toxicity of the Apollo 11 core sample could mean that the deeper one digs the more toxic the soil becomes, but Dr. Taylor concedes that so little is known that the opposite could also be true.

Nothing is yet known for sure about the native moon soil, stresses Dr. Young. Scientists opposing quarantine have claimed that soil from deep within the lunar regolith has been studied on the surface. Dr. Young points out that they really don't know yet the depths of the mixing process.

Dr. Allan H. Brown, chairman of the final NAS review committee, stated before the final decision that his board would "vote one way or the other for good scientific reasons—and not give up quarantine because it is expensive or because the astronauts do not like it," or because it delays delivery of lunar sample material. □