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Case commentary analysis

American Government scientists: availability as expert witnesses in private litigation concerning pharmaceutical product injuries

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One of the major assets of the scientific, medical, and public health communities of the United States is the Federal Government's Centers for Disease Control (CDC) in Atlanta. The Centers bring together biomedical and epidemiological resources recognized for excellence throughout the world. Much of the research data, epidemiological surveillance, and human scientific talent collected at CDC cannot be found or easily duplicated in private industry or in academic research centers. Should this government-based resource and this information be available to help the judicial system and private litigators?

This is a question that has long concerned this writer over the past three decades working with CDC programs and with public health and medical science litigation in the United States and around the world.

Over all of these years, it has been the policy of the Federal establishment that government-employed officials, including scientists, shall not be available voluntarily or by court subpoena to testify in private litigation. This position was upheld 40 years ago by the United States Supreme Court concerning employees of the Federal Department of Justice [1]. The Department of Health and Human Services (where CDC is currently placed) has adopted regulations denying testimony or the production of documents by Department employees unless the Department finds such "compliance" (with a request or subpoena) would "promote the objectives" of the Department [2]. This regulation has been applied to CDC scientists who are sought as witnesses in private litigation. CDC declines to allow its employees to answer most requests or subpoenas from attorneys in private litigation, but the rule is not absolute. Over the years, scientific staff I have talked with tend to stress as the reason for refusal a policy of wishing to stay neutral in judicial disputes rather than to raise the more obvious point of the expenditure of time and effort such involvement would entail.

In regard to neutrality, the agency would seem neither to desire to be seen as overly eager to assist the pharmaceutical or other industrial firms who may make

frequent requests for testimony and records, nor to answer the more isolated, one-time requests of "common citizens" bringing product liability or malpractice suits.

There could, of course, be other less outspoken factors that could contribute to support of CDC policy. Government laboratory personnel and epidemiologists at CDC may not be looking forward to joining the bruising verbal battles, the combative give and take, that are the everyday fare of American courtrooms. Perhaps most resented may be what are often seen as the personal assaults in cross-examination concerning adequacy of training or experience, or questions about potential bias or conflict of interest.

The particular case [3] that gave rise to the judicial examination of the Departmental and CDC policy was a very serious matter in today's American medical and legal scene [4–6]. The plaintiffs were the parents of three hemophiliac children infected with HIV due to receiving transfusions of an infected blood-clotting agent. These children are among thousands of tragic victims of this condition resulting from earlier use of the clotting factor drawn from perhaps millions of human blood donations over a period of years before the HIV could be detected and eliminated. (Any single reception of clotting agent would involve multiple samples from thousands of donors.)

The lawsuits were several product-liability claims against Armour Pharmaceuticals Company and Cutter Laboratories, the latter a division of Miles Laboratories, Inc. The plaintiffs alleged negligence in a failure adequately to screen the donated plasma and Factor VIII manufactured from the plasma and a failure to warn of the risk in receiving the clotting factor at the time of the children's infection.

During the litigation, these plaintiffs issued subpoenas for depositions (sworn examinations out of court) of two physicians, Drs. Bruce Evatt and Donald Francis, both of CDC. The two scientists had been involved extensively in the work of CDC with the AIDS epidemic and efforts to protect the blood supply. Both had published data and recommendations in this area and had spoken at public meetings about procedures related directly to the issues involved in the lawsuits against Armour and Cutter. It was alleged that the two experts had knowledge that was not available through official publications.

The Department of Health and Human Services refused the subpoenas. The reasons expressed for following the policy can be summarized under four headings:

1. The CDC had received so many requests for testimony in AIDS-related litigation that all requests could not be granted.
2. The requests involved a great burden on the work schedule of CDC.
3. The depositions could compromise Departmental policy to remain neutral in private court cases.
4. The Department was concerned that "allowing its employees to get into the conflict of private litigation could harm frank, free, and full exchange within the scientific community".

The case was being heard before the United States Court of Appeals (for the Eleventh Circuit) on appeal from a District Court in Georgia. Judge Dubina, on behalf of a three-judge bench, was, at the outset of the opinion, sympathetic to the

plaintiffs' needs for the deposition testimony. It was indicated that the Federal Rules of Civil Procedure "strongly favor full disclosure whenever possible". Nevertheless, the Court quickly made it clear that it would not overturn the Department's decision. The general policy was upheld with a reference to the Supreme Court holding cited earlier in this article. Also, the Court noted a more recent Court of Appeals opinion restating support of the Federal position [7].

Rather than going into all of the grounds listed above, Judge Dubina concentrated his specific finding upon one point: the administrative burden of answering the many requests for testimony during this epidemic. The most significant language of the opinion upholding the lower court's refusal to allow the subpoenas to go forward was as follows:

> "The primary concern underlying the district court's decision to quash the subpoena was the CDC's interest in conserving the time and attention of its employees for the fight against AIDS. The plaintiffs' interest... simply cannot compare to the government's interest in maximizing the use of its limited resources in dealing with a national health crisis."

If these remarks are not convincing enough, consider the last sentence of the same paragraph. Judge Dubina concluded:

> "Each day that Dr. Evart and other doctors employed by the CDC spend giving testimony is a day they are kept from doing research that might save numerous lives."

The Court also examined the particular information sought in the subpoena. (At this point, only Dr. Evart's deposition was still being requested.) Judge Dubina found the demand too broad. It requested that the expert witness give information about the developing position over time of CDC concerning the epidemic and the methods for screening blood and blood components. The judge expressed the view that such a deposition "could take weeks, if not months" to complete.

The Court in this case did not take an opportunity to express limitations on its sweeping support of the CDC policy in this litigation. However, it should be noted that Judge Dubina did say: "While HHS cannot put a blanket ban on all requests for testimony, there is no question that in this case, its actions were justified".

This statement of the Court makes one believe that each request for deposition or courtroom testimony will be examined by federal judges. The only exception to the general policy of HHS and CDC to refuse requests is where answering would promote the Department's *own objectives*. This seems a quite "blanket ban" on testimony that would tax the human resources of the agency. When can we expect a different position?

It does seem, from past practice, not reviewed at all by the Court, that the CDC will allow its scientists and physicians to provide testimony in private litigation when clear scientific principles are in danger of being fraudulently misrepresented, or when CDC's own policies or its data are in danger of being compromised or misrepresented. For example, the CDC did allow its scientists to testify in several private lawsuits against polio vaccine manufacturers when the CDC had direct evidence that the strain involved in the plaintiff's infection was natural in the community and could not have come from the vaccine itself. The CDC had in its laboratories samples of all strains used in the manufacturer's vaccines and could

specifically compare these vaccine strains with the infection in the litigated case [8]. In later years, CDC reports and testimony have helped to sort out complex liability issues in epidemiological areas and product liability cases [9–11].

It remains to be seen how the *Moore* case will be interpreted in later challenges to CDC's policy. The language of the Court is so strong that later challenges will probably be discouraged. We can hope, however, that the Department and CDC will continue to allow its experts to contribute to important litigation when time does allow such involvement. Depositions are usually much more conveniently arranged than courtroom appearances. Nevertheless, depositions do allow for valuable sworn statements as well as cross-examination by the opposing party or parties in the cases.

We would be most disturbed if the sweeping endorsement of the Court in the *Moore* case encouraged CDC to alter its policy and prevent all involvement of its employees in private litigation. The previous practice of seeking to combat serious scientific error where CDC's own exclusive data could be significantly utilized was a good standard. We can hope that this sensible position will be continued in the future.

References

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8 See, for example, the conflicting policies expressed in Reyes v. Wyeth Laboratories, 498 F. 2d 1264 (5th Cir., 1973).
9 See, for example, in re Swine flu immunization products liability litigation, 508 F. Sup. 967 (1981).
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