MEMORANDUM

TO: Clients and Friends
FROM: Richard Wolfram
DATE: June 3, 2008

Summary of Connecticut Attorney General's Antitrust Investigation and Settlement Regarding IDSA Guidelines for the Treatment of Lyme Disease

In November 2006, the Connecticut Attorney General commenced an investigation of alleged exclusionary and collusive conduct by the Infectious Diseases Society of America (IDSA) with respect to the IDSA's guidelines for Lyme disease. The investigation was opened following advocacy that Lorraine Johnson and I undertook on behalf of the California Lyme Disease Association (of which Ms. Johnson, an attorney, is executive director), several other patient advocacy associations around the country and related interests.

Legal argument. It was our position that if members of a medical guidelines panel (or their medical association) are economically interested in the outcome of a guideline; if the guideline effectively has mandatory effect; if the procedural integrity of the guideline development process is suspect, either from the point of view of the internal rules of the medical association or more general standards of due process; and if these factors substantially suppress competition through foreclosure of an arguably legitimate treatment option – then antitrust principles of exclusionary conduct through standard setting may come into play and the association's guideline activity should be subject to legal scrutiny.

The investigation. Antitrust and health care attorneys in the AG's Office brought their considerable expertise to bear on these issues, based on nearly a decade of experience with legal, scientific and social questions surrounding the disease.

The investigation focused on guidelines developed by IDSA panels in 2000 and 2006 for the treatment of Lyme disease, a sometimes debilitating, tick-borne disease common in the Northeast and present in other parts of the U.S. and also in Europe.

Central dispute: chronic Lyme disease. Most controversially, the guidelines conclude that the condition known as chronic Lyme disease – with patients suffering a range of ill effects for months and even years – has no basis in scientific fact. This conclusion is based on the view that the spirochete that carries the disease does not persist in the body long-term. As a result, the guidelines state that treatment with a course of antibiotics beyond 30 days is not appropriate and that persistent symptoms represent at most a post-disease syndrome.

Furthermore, the guidelines effectively deny the use of clinical discretion by physicians in the diagnosis and treatment of Lyme disease and provide no additional treatment options, apart from palliative treatment, for patients who fail to improve under

the IDSA 'recommended' protocol. Although a substantial body of scientific and empirical studies reports that long-term antibiotic treatment can indeed be effective and that the spirochete can persist in the body notwithstanding 'standard' courses of antibiotics, these findings are dismissed by the IDSA as unsubstantiated. Most insurance companies, citing the IDSA guidelines in support, deny coverage for antibiotic treatment beyond 30 days.

Findings of the Attorney General. According to the Attorney General's Press Release, the investigation found that there were "significant procedural deficiencies related to the IDSA's development of its 2006 Guidelines" and that the panel and the IDSA itself failed to ensure that the guideline development comported with due process, as required by antitrust law when persons involved in standard setting (or their association) have an economic interest in the outcome. In particular, the AG said, the panel "improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science."

The AG also found that:

▪ key panel members had significant conflicts of interest in drug companies (regarding vaccine development), Lyme disease diagnostic tests, patents and consulting arrangements with insurers; these individuals "exclude[d] divergent medical evidence and opinion; and their economic interests were consistent with the guidelines' curtailment of recommended treatment beyond 30 days of antibiotics;[1]

▪ the IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the guideline panels;

▪ the IDSA did not comply with its own guidelines for selecting a panel chair, "enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;"

▪ the IDSA's 2000 and 2006 panels "refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease;"

▪ the IDSA "remov[ed] a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve 'consensus';"

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[1] Conflicts of interest in medical guidelines typically relate to panel members' commercial interests in drugs used for *treatment*. That kind of kind of economic interest, however, is irrelevant in this matter; it is not alleged that any panelists had economic interests in antibiotic drugs (which are generic, in any case) and of course even if they did, such an interest would not be promoted by guidelines that reject long-term antibiotic treatment. Here, the relevant alleged conflicts pertain instead to panelists' commercial interests related to vaccines, diagnostic tests and insurance. Guidelines that restrict the disease definition favor vaccine manufacturers because the guidelines increase the statistical rate of efficacy of the vaccines, so that fewer people taking the vaccine contract the disease. Guidelines that mandate testing for disease diagnosis promote the interests of those who develop and manufacture diagnostic tests: here, the mandated testing is widely alleged to be flawed and the guidelines effectively deny that patients manifesting long-term symptoms are suffering from Lyme disease because they test 'negative' based on that testing. Finally, guidelines that effectively deny treatment to patients are favorable to insurance companies and those who are paid to consult with them.

▪ the IDSA "blocked appointment of scientists and physicians with divergent views on chronic Lyme;"

▪ the IDSA improperly sought to portray a second set of Lyme disease guidelines, issued by the American Academy of Neurology, as independently corroborating its findings, when in fact the IDSA knew that the two panels shared key members, in violation of the IDSA's own conflicts of interest policy; and

▪ a number of insurers have used the guidelines as justification for denying reimbursement for long-term antibiotic treatment.

The investigation also considered evidence that doctors wishing to reserve the option to treat with long-term antibiotics increasingly face the prospect of professional misconduct sanctions and the loss of hospital privileges; that as a result of the chilling effect of the guidelines and the prospect of professional misconduct actions, far fewer doctors are willing to provide long-term antibiotics to people suffering from long-term symptoms of Lyme disease; that the guidelines substantially foreclose clinical discretion regarding long-term antibiotic treatment; and that the resulting suppression of output and sharply limited reimbursement by most insurance companies in turn have virtually foreclosed or made prohibitively expensive long-term antibiotics as a feasible treatment option for significant numbers of patients, leaving them with only the palliative treatment option recommended by the IDSA guidelines.

Settlement agreement: a possible "model." Under the settlement agreement, the IDSA will form a new panel to reassess the guidelines. An ombudsman, who is a specialist in medical ethics and conflicts of interest and director of the Institute for Medical Humanities at the University of Texas Medical Branch School at Galveston, will be responsible for ensuring that no panel members have financial conflicts of interest. Physicians and researchers will make formal, public presentations to the panel, which will be aired live over the internet. The panel will then determine by supermajority vote whether the science supports the guideline recommendations. The panel may vote to make no changes, modify the guidelines or replace them entirely. The Connecticut Attorney General retains general oversight over the process, to ensure compliance with the settlement agreement.

The Connecticut Attorney General emphasized that the investigation "was always about the IDSA's guideline process – not the science." He added that the remedy, "the Action Plan – incorporating a conflicts screen by an independent neutral expert and a public hearing to receive additional evidence – can serve as a model for all medical organizations and societies that publish medical guidelines. This review should strengthen the public's confidence in such critical standards."

Situating the settlement in the context of related developments: News of related developments helps put the Connecticut investigation and settlement into context. Recent years have seen an increasing number of revelations about financial conflicts of interest on the part of medical guidelines panelists, where those financial interests may have influenced the panels to reach incorrect or suspect results. This development has been widely reported on and is the subject of a growing body of scientific and public policy

literature.[2] At the same time, guidelines increasingly have come to influence the practice of medicine and to limit clinical discretion.

Also, of course, the potential anticompetitive risks of mandating a treatment approach through guidelines are heightened when the guidelines are issued by the dominant medical association within a given specialty area. As Attorney General Blumenthal said, with reference to his investigation of the IDSA, "[i]n today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions."

The Connecticut Attorney General's investigation and settlement with the IDSA has put these issues squarely into the spotlight – and captured national media attention – most particularly because it has brought to the fore the potential antitrust implications of medical guideline development.

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[2] *See, e.g.,* Jerome Kassirer, *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health* (Oxford University Press 2004).

Recent prominent examples of commercial conflicts of interest influencing guidelines include the National Kidney Foundation's panel that recommended erythropoietin in 2006 (see accompanying *Wall Street Journal* article), the American Society of Hypertension's panel in 2006 that narrowed the parameters of "normal" blood pressure while prominent panel members stood to benefit from increased sales of blood pressure-lowering drugs, and numerous examples of psychiatrists serving on guideline panels while benefiting financially from work on behalf of pharmaceutical companies making psychiatric drugs, as reported in several stories in *The New York Times* in the summer of 2007.