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# Regulating Access to Developmental Drugs for Terminally Ill Patients: Abigail Alliance v FDA

**John E. Calfee, Daniel B. Klein, Sam Peltzman,
Alex Tabarrok, Benjamin Zycher**

**Brief 07-01
January 2007**

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CASE NO. 04-5350

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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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ABIGAIL ALLIANCE FOR BETTER ACCESS
TO DEVELOPMENTAL DRUGS, *ET AL.*,

Appellants,
v.

ANDREW C. VON ESCHENBACH, *ET AL.*,

Appellees.

---

ON APPEAL FROM THE DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

---

**BRIEF FOR ECONOMISTS JOHN E. CALFEE, DANIEL B. KLEIN, SAM PELTZMAN, ALEX TABARROK, AND BENJAMIN ZYCHER AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS AND WASHINGTON LEGAL FOUNDATION**

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## Certificate As To Parties, Rulings, And Related Cases

Pursuant to Circuit Rule 28(a)(1)(A), the undersigned counsel of record certifies as follows:

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(B) **Ruling Under Review.** References to the ruling at issue appear in the Brief for Appellants.

(C) **Related Cases.** None.

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## INTEREST OF AMICI CURIAE

*Amici* are economists and economics professors who teach and write in the area of pharmaceutical regulation and health care policy, and who wish to ensure that the Court fully considers the adverse effects the institutional failures at the Food & Drug Administrative ("FDA") have had on public health. *Amici* have no stake in the outcome of this case. They are filing this brief solely as individuals and not on behalf of the institutions with which they are affiliated.

John E. Calfee is a Resident Scholar at the American Enterprise Institute. He has written extensively on FDA policy, health care policy, and the pharmaceutical and drug markets. Dr. Calfee is the author of many publications on pharmaceutical and health care issues. *See, e.g.,* John E. Calfee, PRICE, MARKETS, AND THE PHARMACEUTICAL REVOLUTION (2000). Dr. Calfee previously was a visiting fellow at the Brookings Institution, and an associate professor at the Boston University School of Management.

Daniel B. Klein is Professor of Economics at George Mason University and an Associate Fellow at the Ratio Institute in Stockholm, Sweden. Professor Klein has published extensively on the ways that private, voluntary institutions respond to the natural demand for quality-and-safety assurance. *See, e.g.*, REPUTATION: STUDIES IN THE VOLUNTARY ELICITATION

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Sam Peltzman is the Ralph and Dorothy Keller Distinguished Service Professor Emeritus of Economics at the University of Chicago Graduate School of Business. He has written extensively on the economics of regulation and government activity, including the first empirical studies of the effects of Food and Drug Administration regulation. *See, e.g.*, Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049 (1973); SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974). The "Peltzman effect," which arises when people adjust their behavior to a regulation in ways that counteract the intended effect of the regulation, is named after Professor Peltzman.

Alex Tabarrok is Associate Professor of Economics at George Mason University, research director for The Independent Institute and a Research Fellow with the Mercatus Center. Professor Tabarrok has written extensively on health economics, including drug regulation by the FDA. *See, e.g.*, Alex Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescriptions*, INDEP. REV., Summer 2000, at 25; Daniel B. Klein & Alex Taborrok, *Time to End America's Drug Lag*, 85 CONSUMERS' RES. MAG. 10 (2002); Daniel B. Klein & Alex Taborrok, *Who Certifies Off-Label?*, REGULATION, Summer 2004, at 60.

Benjamin Zycher is a Senior Fellow at Manhattan Institute's Center for Medical Progress. Dr. Zycher is a former senior economist at the RAND Corporation, a former vice president for research at the Milken Institute, and a former member of the Board of Directors of the Western Economic Association International. He is also a former adjunct professor of economics at the University of California, Los Angeles and the former editor of the quarterly public policy journal Jobs & Capital. Dr. Zycher was a senior staff economist at the President's Council of Economic Advisers during the first two years of the Reagan Administration. Dr. Zycher's research focuses on the economic and political effects of regulation. He has

done considerable work as well on health care policy and the economics of the pharmaceutical sector.

*Amici* take no position on the knotty constitutional questions of the due process clause that confront this Court, other than to note that the guidance of the Supreme Court has been opaque and inconsistent. *Compare Stenberg v. Carhart*, 530 U.S. 914, 937 (2000) (unconstitutional to bar controversial medical procedure that is "necessary, in appropriate medical judgment, for the preservation" of life or health because state must "tolerate responsible differences of medical opinion") *with Washington v. Glucksberg*, 521 U.S. 702, 792 (1997) ("That many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected."). *Cf. also* Laurence H. Tribe, *The Treatise Power*, 8 GREEN BAG 2d 291 (2005). *Amici* also take no position on the question of standing.

Rather, *amici* argue that the original panel's decision, since vacated, presents no danger to public health and, in fact, would improve public health outcomes. Empirical experience—both from the United States and abroad—shows that the lengthy delays typically associated with FDA drug approvals do not demonstrably improve the public health outcomes. Moreover,

providing seriously-ill patients with access to potentially life-saving drugs after Phase 1 approval will not discourage further clinical testing. Put simply, the decision of the original panel will enhance, rather than jeopardize, public health. Therefore, pursuant to Federal Rule of Appellate Procedure 29 and this Circuit's Rule 29, *amici* respectfully request that the Court affirm the decision of the original panel.

## SUMMARY OF ARGUMENT

This case concerns a systematic administrative breakdown that has for decades unnecessarily prevented terminally-ill patients from having access to drugs that have demonstrated a reasonable measure of safety and efficacy in FDA-approved trials. The FDA's long history of withholding clinically-tested and potentially life-saving drugs from the market because of institutional failures renders any legal justification for these delays highly suspect. In short, the legal question at the heart of this case is not whether Due Process requires the FDA to provide terminally-ill patients with access to unsafe drugs—by definition, the post-Phase 1drugs at issue here have already achieved a preliminary safety determination. Rather, the question is whether the Court should permit the FDA to erect an administrative obstacle that, through delay, prevents useful drugs from reaching patients with no remaining treatment option. It is this administrative failure—and not the

discretion of the agency to determine the safety of new drugs in the first instance—that lies at the heart of this case.

Phase 1 trials traditionally focus on *drug safety*, including understanding the "metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses [and] the drug's pharmacokinetics and pharmacological effects." 21 C.F.R. § 312.21(a). By contrast, Phase 2 and Phase 3 trials focus on *drug effectiveness* while gathering additional safety information. *Id*. § 312.21(b) ("Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study."); *id*. § 312.21(c) (Phase 3 trials "are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."). In oncology, however, Phase 1 trials typically reveal essential data on benefits as well as risks. Manish Agrawal & Ezekiel J. Emanuel, *Ethics of Phase 1 Oncology Studies: Reexamining the Arguments and Data*, 290 J. AM. MED. ASS'N 1075 (2003). Preventing terminally-ill patients from pursuing potentially life-saving treatments until effectiveness has been thoroughly substantiated ignores the

fact that for patients with no remaining treatment options, any significant, evidence-based chance of an effective outcome may be worth taking.

The FDA's motivation for its unfounded delay in releasing safe drugs stems from an institutional desire to avoid potentially negative public opinion. There are two types of errors that can be made in deciding whether to permit new drugs to be sold: erroneously identifying drugs as reasonably safe that are in fact unsafe, and refusing to permit the sale of drugs that are in fact reasonably safe. These errors are known as Type I errors and Type II errors, respectively. In arguing for reconsideration, the FDA suggested that releasing post-Phase 1-approved drugs to volunteers would risk exposing terminally-ill patients not only to inefficacious cancer treatments, but also to potentially unsafe side effects—a classic Type I error. But the FDA's institutional incentives to exercise excessive caution in approving new drugs, even if rational and well-informed patients would want access to such drugs, is not always consistent with patient welfare. Empirical evidence strongly suggests that the FDA historically has been over-concerned with avoiding Type I errors while underestimating the damaging public health consequences of the Type II errors that affect patients such as the members of the Abigail Alliance.

Moreover, removing the administrative barriers that the FDA has erected between terminally-ill patients and potentially life-saving Phase 1-approved drugs prescribed pursuant to medical professional judgment will not discourage further clinical testing of such drugs. The widespread prescription of "off-label" drugs has not discouraged further testing of those drugs through random clinical trials while the drugs remained under patent protection. Similarly, there is no reason to doubt that patients will continue to participate in randomized clinical trials for unapproved cancer drugs even if those drugs are made available outside of clinical trials, or that pharmaceutical research firms will continue to fund clinical trials for drugs that are already available to patients.

Delaying drug approvals for years after the initial safety determination purely because of institutional risk aversion does not improve upon individual risk-benefit decisions or indeed advance public health writ large. The original panel decision did not undermine the process for scrutinizing investigational new drugs. Nor did it compromise the robust incentives for patients to participate in post-Phase 1 trials or for manufacturers to fund such research. It merely removed an indefensible administrative obstacle for a limited class of terminally-ill patients for whom there is no alternative treatment option. If the more onerous provisions of FDA regulation were

found unconstitutional, public health would be better off. Whatever the merits of the FDA's legal position, Abigail Alliance's position redounds best to the public health.

## ARGUMENT

### I. The Food & Drug Administration Has Historically Been Too Slow To Approve New Treatments.

Economists and others have long argued that FDA staff incentives are skewed toward excessive caution in the regulation of drug development and the approval of new drugs. When deciding whether the benefits of a proposed new drug exceed its risks, FDA staff well know that if they commit a Type I error—the approval of a drug that turns out to be insufficiently safe once marketing begins—their error will become known. Because the harmful or deadly side-effects of the drug may be highly visible, a Type I error can and often does lead to impassioned criticism of the agency. For example, the swine flu vaccine approved by the FDA in the mid-1970s proved effective at preventing influenza but resulted in hundreds of well-publicized cases of death or paralysis from Guillain-Barré syndrome. On the other hand, a Type II error—the failure to permit marketing of a drug that would in fact provide benefits in excess of harms—is typically detected only by the relatively few persons who are intimately involved in developing a drug with which patients and the larger medical community have no

practical experience. Yet the public health consequences of a failure to approve a beneficial drug may be even more severe than the approval of an insufficiently safe drug. Type I errors are often quickly corrected precisely because insufficiently safe drugs cause public problems. But the failure to approve a beneficial drug may go uncorrected for years. As a result, the net effect of the asymmetry in publicity is to bias even the best-intentioned FDA regulators towards excessive caution and delay in approving new drugs. *See, e.g.*, Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049 (1973), *reprinted in* CHICAGO STUDIES IN POLITICAL ECONOMY 303-48 (George J. Stigler ed., University of Chicago Press 1988); SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974); WILLIAM M. WARDELL AND LOUIS LASAGNA, REGULATION AND DRUG DEVELOPMENT (1975); Kenneth Kaitin & Jeffrey Brown, *A Drug Lag Update*, 29/2 DRUG INFO. J. 361-374 (1995); HENRY I. MILLER, TO AMERICA'S HEALTH: A PROPOSAL TO REFORM THE FOOD AND DRUG ADMINISTRATION (2000).

If the FDA's overly cautious approach helped avoid the approval of unsafe drugs, one would expect more rapid drug approval timelines to result in a greater number of post-approval drug withdrawals. But the facts are to the contrary. For example, the United States, Spain and the U.K. have

yielded essentially identical drug withdrawal rates despite the more rapid drug approval timelines in the European countries. Olav M. Bakke, et al., *Drug Safety Discontinuations in the United Kingdom, the United States, and Spain from 1974 through 1993: A Regulatory Perspective*, 58 CLINICAL PHARMACOLOGY AND THERAPEUTICS 108 (1995) (noting post-approval drug withdrawals of, respectively, 3% in U.S. and Spain, 4% in U.K.). In addition, a recent Institute of Medicine report on drug safety and the FDA found no apparent diminution in drug safety resulting from faster new drug approvals since 1992. INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 3: 5-8 (2006) (reviewing the effects of the Prescription Drug User Fee Act of 1992). In short, the FDA's administrative delay in approving new drugs has produced few tangible reductions in new drug-related public health risks.

Recent debate over the FDA's handling of drug safety, notably in connection with SSRI antidepressants and Vioxx, an arthritis pain reliever, and culminating in a recent report from the Institute of Medicine, has made clear that the institutional incentives to avoid Type I errors at the expense of committing more Type II errors remain very strong. Criticism of FDA staff in connection with the safety of recently approved drugs vastly exceeds any criticism of agency sluggishness in approving the hundreds of drugs in

development in recent years. John E. Calfee, *The Vioxx Fallout*, AEI HEALTH POLICY OUTLOOK, Sept.-Oct. 2005; INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC (2006); John E. Calfee, *Playing Catch-up: The FDA, Science, and Drug Regulation*, AEI HEALTH POLICY OUTLOOK, March 2006.

Because of the strong institutional incentives to avoid Type I errors, it cannot be assumed that the FDA's assessment of the relative risks and benefits of drugs during the development stage is correct or even unbiased. Rather, the FDA tends to be too conservative, often waiting far too long to release new drugs for marketing despite favorable results in Phase 1 trials. For example, a recent analysis of Phase 1 oncology drug trials, when drugs are still far from FDA approval, concluded that "the risks and benefits of Phase 1 trials are not clearly worse than risk-benefit ratios used by the US Food and Drug Administration to approve chemotherapeutic agents for clinical use." Manish Agrawal & Ezekiel J. Emanuel, *Ethics of Phase 1 Oncology Studies: Reexamining the Arguments and Data*, 290 J. AM. MED. ASS'N 1075 (2003). Stated differently, seriously-ill patients who choose to voluntarily access Phase 1-approved drugs may face no greater treatment-related risk than patients accessing those drugs after years of random clinical testing.

In addition to overstating potential risks, the FDA also systematically underestimates the potential benefits terminally-ill patients would gain from unapproved drugs that achieve favorable results in Phase 1 trials. For many patients, such drugs present a window of opportunity that has been closed off by FDA regulation. The disparity between patients' assessment of risks and benefits, compared to the FDA's, was detailed in a recent *New England Journal of Medicine* editorial on the risks and benefits of Phase 1 oncology drug trials: "The intense lobbying efforts of activists for earlier access to experimental therapies for AIDS and breast cancer are further evidence that patients facing inevitable death may be less risk-averse than is the regulatory community." Razelle Kurzrock & Robert S. Benjamin, Editorial, *Risks and Benefits of Phase 1 Oncology Trials, Revisited*, 352 NEW ENG. J. MED. 930 (2005). Widespread patient acceptance of off-label prescribing, which accounts for the majority of oncology drug prescriptions, is further evidence that patients—particularly terminally-ill patients—are willing to accept risks involved in uses unapproved by the FDA.

In short, empirical evidence strongly suggests that the FDA's drug approval process has not only failed to systematically improve the risk-benefit profile of new drug approval, but may have harmed public health by unnecessarily delaying beneficial new treatments from the market.

## II. Permitting Terminally-Ill Patients To Access Potentially Life-Saving Post-Phase I Approval Drugs Will Not Discourage Participation In Randomized Clinical Trials.

Despite the dire warnings from the FDA in this litigation, there is no danger that the decision of the original panel will discourage broad patient participation in post-Phase 1 clinical trials. In fact, experience shows that post-Phase 1 research proceeds even when the drugs being investigated are readily available. For example, a long series of post-approval trials of the statin class of cholesterol-reducing drugs—currently among the most prescribed classes of drugs worldwide—has greatly expanded scientific knowledge of the role of serum cholesterol in heart attacks and strokes. Because these trials were often designed to demonstrate the ability of drugs to prevent relatively uncommon events, such as heart attacks among patients who are not at very high risk, many of these trials have been very large, involving tens of thousands of patients. Eric Topol, Editorial, *Intensive Statin Therapy: A Sea Change in Cardiovascular Prevention*, 350 NEW ENG. J. MED. 1562 (2004). Roughly half of the participants in these trials received arguably inferior alternative treatments even though the drugs being tested were already widely prescribed and were known to virtually all practicing physicians. Patients were willing to enter these trials even after being

informed of these circumstances and despite the availability of the drugs outside of trials.

In the universe of oncology treatment, post-approval trials are becoming standard practice. Most new cancer drugs, such as Erbitux, Herceptin, Avastin, Gleevec, and Rituxan, are tightly targeted at precise biological mechanisms. Often, the most efficient way to bring these drugs through the FDA approval process is to test them against a specific late-stage cancer, such as metastatic breast cancer. Success in such trials can bring fairly quick FDA approval, but research on broader uses for the treatment often continues after approval. Such post-approval research typically explores earlier stages of the cancer (e.g., Herceptin), other cancers in which the same targeted biological mechanism is involved (such as Gleevec for gastrointestinal stromal tumors rather than its original indication for chronic myeloid leukemia), and even entirely different illnesses involving similar biological mechanisms. For example, the cancer drug Avastin has been included trials for more than twenty different cancers or alternative treatment modalities (such as with or without older drugs). Michael Flanagan, *Avastin's Progression*, BIOCENTURY, March 6, 2006, at A1. And while originally approved for cancer treatment, the FDA recently approved Rituxan for rheumatoid arthritis treatment based on post-approval

testing. John E. Calfee & Elizabeth DuPré, *The Emerging Market Dynamics of Targeted Therapeutics*, 25 HEALTH AFF. 1302 (2006).

In most if not all of these post-approval trials, participants could have been prescribed the drug without entering into the trials. The sheer number of patients involved in post-approval trials is evidence of the widespread willingness of patients to enroll in randomized trials of drugs that are readily available outside of clinical trials.

## III. Affirming The Decision Of The Original Panel Will Not Reduce Incentives For Manufacturers To Conduct Randomized Clinical Trials Of Available Drugs.

The fact that patients readily enroll in clinical trials of approved drugs highlights the willingness of research firms to bear the significant expense of conducting such trials. Manufacturers have strong market incentives to conduct post-approval trials that operate in addition to, or independently of, FDA regulation. For example, post-approval trial results are sometimes used to obtain a Supplemental New Drug Approval (SNDA) from the FDA, thus expanding the range of FDA-approved uses for an approved drug. This is by no means always the case, however, partly because FDA has historically been quite slow in reviewing supplemental indications. Joseph A. DiMasi, Jeffrey S. Brown & Louis Lasagna, *An Analysis of Regulatory Review Times of Supplemental Indications for Already-Approved Drugs:*

*1989-1994*, 30/2 DRUG INFO. J. 315 (1996). Such research findings are among the many resources relied upon in off-label prescribing, an increasingly common practice in the field of oncology. S. Thakkar, *Oncologists Judge Themselves the Best Judges of Cancer Treatments*, 16 J. NAT'L CANCER INST. 1188 (1997). Indeed, off-label prescribing has been endorsed by FDA, the National Cancer Institute, and the American Society of Clinical Oncology, an organization of oncology practitioners and researchers. *See, e.g., More Information for Better Patient Care: Hearings before the Committee on Labor and Human Resources*, United States Senate, 104th Congress, 64-73, 81-88 (Feb. 22, 1996) (testimony of William B. Schultz); NATIONAL CANCER INSTITUTE, UNDERSTANDING THE APPROVAL PROCESS FOR NEW CANCER TREATMENTS (2004), *available at* http://newscenter.cancer.gov/clinicaltrials/ learning/approval-process-for-cancer-drugs/allpages/print. Oncology physicians, in particular, have vigorously defended off-label prescribing as redounding strongly to the benefit of patients. American Society of Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications,* J. CLINICAL ONCOLOGY, July 1, 2006, at 1. The widespread phenomenon of off-label prescribing and the critical attention paid to the evidentiary support for such practices create strong incentives for manufacturers to conduct high-quality

research on unapproved drugs that have passed Phase 1 trials. Alex Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescriptions*, INDEP. REV., Summer 2000, at 25.

Other post-approval trials are intended not so much to support FDA approval of supplemental indications as to provide objective evidence for professional groups, hospitals and clinics, and individual physicians and patients when they are deciding how to use the approved drugs. One manufacturer in particular, Pfizer, reported that as of 2003, its cholesterol drug Lipitor, first approved in 1998, had been tested in more than 400 current or completed trials involving more than 80,000 patients. Andrew Humphreys & Charles Boersig, *Cholesterol drugs dominate: Lipitor and Zocor maintain their leading positions in the group of 200 best-selling prescription medicines.*, MED. AD. NEWS, May 1, 2003 at 1. Major new trial results have since been presented on both heart attacks and strokes. John C. LaRosa, et al., *Treating to New Targets (TNT) Investigators, Intensive Lipid Lowering with Atorvastatin in Patients with Stable Coronary Disease*, 352 NEW ENG. J.MED 1425 (2005); David M. Kent, Editorial, *Stroke: An Equal Opportunity for the Initiation of Statin Therapy*, 355 NEW ENG. J. MED. 613 (2006). In the oncology field, extensive, and presumably expensive, post-approval research on newer cancer drugs has explored the ability of

approved drugs to treat relatively rare but deadly cancers, such as pancreatic cancer. Peter Loftus, *Hunt for Improved Pancreatic-Cancer Drug Continues*, WALL ST. J., Dec. 27, 2006, at D7 (discussing trial results for the cancer drug Erbitux for the treatment of pancreatic cancer).

All told, providing seriously-ill patients with access to Phase 1-approved drugs will in no way undercut the tremendous economic incentives of manufacturers to fund and conduct critical, later stage testing on new drugs.

## CONCLUSION

Phase 1 approval by the FDA reflects the agency's traditional approach to balancing the risks and benefits of new drugs, but Phase 1 data often reveal drugs that are of great potential value to patients who lack any alternative treatments. The panel majority correctly refused to countenance the further administrative obstacles erected by the FDA, which result in long and unjustified Phase 2 delays in authorizing Phase 1-approved—and potentially life-saving—drugs. These delays flow from the FDA's bias for committing overcautious Type II errors. The panel majority's decision that Phase 1-approved drugs may not be withheld from terminally-ill patients will not interfere with the FDA approval process; to the contrary, patients will continue to participate in randomized clinical trials of available drugs,

and manufacturers will continue to have incentives to mount randomized clinical trials of available drugs.

For the foregoing reasons, the decision of the original panel should be affirmed.

Dated: January 11, 2007 Respectfully Submitted,

_____

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## CERTIFICATE OF COMPLIANCE

In accordance with Rules 32(a)(7)(B) and (C) of the Federal Rules of Appellate Procedure and Circuit Rule 32(a), the undersigned certifies that the accompanying brief has been prepared using 14-point typeface, proportionally spaced, with serifs. According to the word processing system used to prepare the brief, Microsoft Office Word 2003, the brief contains 4,008 words, exclusive of the table of contents, table of authorities, glossary, attorney identification, and certificates of service and compliance

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## CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of January, 2007, two copies of the foregoing BRIEF FOR ECONOMISTS JOHN E. CALFEE, DANIEL B. KLEIN, SAM PELTZMAN, ALEX TABARROK, AND BENJAMIN ZYCHER AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS was served by first-class mail, postage prepaid, upon the following:

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