No. 07-444

IN THE
Supreme Court of the United States

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

v.

ANDREW VON ESCHENBACH, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, *ET AL.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF *AMICUS CURIAE* OF THE SENIOR CITIZENS LEAGUE IN SUPPORT OF PETITIONERS

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December 13, 2007

TABLE OF CONTENTS

TABLE OF AUTHORITIES

INTEREST OF AMICUS CURIAE

The Senior Citizens League ("TSCL") is a registered d/b/a of TREA Senior Citizens League, a nonprofit, non-partisan social welfare organization, interested in the proper construction and application of the Constitution and laws of the United States.[1] TREA Senior Citizens League is incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. Headquartered in Alexandria, Virginia, TSCL is one of the nation's largest nonpartisan seniors groups with more than 750,000 senior citizen members and supporters, engaging in education and advocacy. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned. It monitors developments in the United States with respect to the interests of senior citizens, defends those interests before government, and develops educational materials designed to explain to seniors their rights as U.S. citizens. TSCL and its members may be directly impacted by this Court's resolution of the issues in this case.

SUMMARY OF ARGUMENT

At stake in this case is whether a terminally ill patient who seeks to preserve his or her life may constitutionally be denied access to a potentially life-saving drug by an administrative process that completely disregards the patient's God-given, inalienable rights to life and liberty.

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[1] The parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the filing date of this *amicus curiae*'s intention to file this brief. No counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission.

Applying this Court's tests as stated in Washington v. Glucksberg, 521 U.S. 702 (1997), the *en banc* court of appeals below found no such God-given right. The Glucksberg tests, however, are erroneous, having been based upon an unwarranted misuse of judicial power that substitutes its ever evolving "reasoned judgment" for the textual meaning of life and liberty in the Fifth Amendment Due Process Clause.

According to the unchanging authorial intent of that Clause, the meaning of life and liberty is fixed, anchored in the "laws of nature and of nature's God," as reflected in the writings of Blackstone's Commentaries and the nation's Charter, the Declaration of Independence, and as confirmed by the law of revelation, the Holy Scriptures.

According to an unchanging Common Law right to life and liberty, a person has the right to choose medical care to preserve one's life, which in this case was unconstitutionally denied to a terminally-ill person by a generalized, impersonal, and flawed administrative process in violation of the Fifth Amendment Due Process guarantee.

ARGUMENT

I. The Narrow Question Presented by Petitioners Is Properly Resolved by Reference to a Broad Constitutional Right.

The question presented by petitioners defines an asserted constitutional right in narrow terms:

> Whether the Due Process Clause protects the right of [i] a terminally ill patient [ii] with no remaining approved treatment options to attempt to save her own life by deciding, [iii] in

> consultation with her own doctor, whether to seek access to [iv] investigational medications that the Food and Drug Administration concedes are safe and promising enough for substantial human testing. [Petition, p. i.]

Configuring the question presented in this manner automatically triggers the thought that the Due Process Clause of the Fifth Amendment certainly would not preserve, as a constitutional right, such a technical claim for such a narrow class of persons.

To be sure, constitutional rights are generally stated in broad, general terms, for the very nature of a constitution is that it does not "partake of a prolixity of a legal code." *See* McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 407 (1819). However, courts do not decide constitutional claims in the abstract, but in response to narrow and specific questions of law presented by the specific facts of a case or controversy that can only be resolved by particular application of broad and general constitutional principles. *See, e.g.*, Meyer v. Nebraska, 262 U.S. 390, at 396-99 (1923). This is one of those cases.

As the dissent in the *en banc* opinion below demonstrated, the essence of petitioners' specific claim of access to a not-as-yet approved drug by the U.S. Food and Drug Administration ("FDA") implicates "the right to attempt to preserve [life]" and "the right to try to save one's life." Abigail Alliance v. Von Eschenbach, 2007 U.S. App. LEXIS 18688, at 60, 61 (Rogers, J., dissenting). The majority, however, narrowed the constitutional question limiting it to the facts of the case: "[W]e must determine whether terminally ill patients have a fundamental right to experimental drugs that have passed Phase I clinical testing." *Id.*, at 14. The majority adopted this narrow phraseology because it claimed that petitioners' constitutional

claim would otherwise not meet the "'careful description' of the asserted fundamental liberty interest," demanded by Washington v. Glucksberg, 521 U.S. 702, 721 (1997). *See* Abigail Alliance, 2007 U.S. App. LEXIS 18688, at 18-19. Yet, by framing the claim so that it is so "inextricably entangled with the details of shifting administrative regulations," the majority shut the door on any possibility that petitioners could prevail on their contention that "the right to access experimental and unproven drugs in an attempt to save one's life" is "deeply rooted in Nation's history," as required by Glucksberg. *Id.* at 16, n.25and 20, n.6.

Contrary to the *en banc* majority, the petitioners anchored that claim not in the FDA "regulatory scheme" (*id.* at 64 (Rogers, J., dissenting)), but in the Due Process Clause, itself. As the dissent pointed out, that due process claim was not based on some "abstract notion of personal autonomy," but on "common law doctrines [evidencing] a history and tradition of protecting life and attempts to preserve life as a deep-seated personal right." *Id.* at 58 and 64 (Rogers, J., dissenting). Thus, petitioners' claim meets the Glucksberg standard requiring a "'careful description' of the asserted fundamental liberty [and life] interest" protected by the Fifth Amendment Due Process guarantee. *See* Glucksberg, 521 U.S. at 721.

II. The Fifth Amendment Due Process Protection of "Life" and "Liberty" Must Not Be Detached from the Constitutional Text.

A superficial reading of the Fifth Amendment Due Process text might suggest that it requires only that certain procedures be followed before the federal government is permitted to impair "life" and "liberty," without defining the content of those terms. But, as this Court observed in its plurality opinion in Planned Parenthood v. Casey, 505 U.S. 833 (1992), "since

Mugler v. Kansas, 123 U.S. 623, 660-61 (1887), the Clause has been understood to contain a substantive component as well, one 'barring certain government actions regardless of the fairness of the procedures used to implement them.'"

However, Casey provides little justification for converting an apparent procedural protection into a substantive guarantee. And, despite the 120-year history of substantive due process cases, one would search in vain for a textual justification for substantive due process. Rather, it simply "has become" an entrenched constitutional doctrine. The foremost reason for this analytical emptiness is the Court's steadfast refusal to tie the meaning of "life" and "liberty" to the Due Process text, as the Casey plurality opinion so clearly reveals:

> The inescapable fact is that adjudication of substantive due process claims may call upon the Court in interpreting the Constitution to exercise that same capacity which by tradition courts always have exercised: **reasoned judgment**.... [Casey, 505 U.S. at 849 (emphasis added).]

Sadly, this analysis divorces the meaning of the Constitution from the text of the Constitution, and in so doing vests virtually unbridled power in the Court to amend the Constitution through means other than those set out in Article V thereto.

Further, while it appears from Casey that the Court has, in the name of due process, claimed to have created an absolute "realm of personal liberty which the government may not enter" (Casey, 505 U.S. at 847), its decisions reveal that there is no such right, whether considered fundamental or not, that is completely beyond the power of government to erode, if there is a "compelling" reason to do so. *See* Glucksburg, 521 U.S. at

721. Thus, the Court's nontextual approach leads not to an enduring and unchanging rule of constitutional law, but to one that changes with changing times and changing personnel on the Court as to what they determine to be "compelling."

In his classic, Validity in Interpretation (Yale University Press, 1967), now retired University of Virginia Professor of Education and Humanities E.D. Hirsch, Jr., has explained to the Court's failure to find enduring rules is clearly a consequence of a 40-year "heavy and largely victorious assault on the sensible belief that **a text means what the author meant**," so that "a so-called **pragmatism** prevails which holds that **the meaning of a law is what present judges say the meaning is.**" *Id.* at viii (emphasis added). Professor Hirsch describes the current practice of substituting the reader's view for that of the author's to be a "usurpation," a "deliberate banish[ment] [of] the original author," creating thereby "our present-day ... confusion" of the true meaning of a text. *Id.* at 5.

In the present case, if the Court were to embark on a genuine search for authorial meaning of the terms "life" and "liberty" in the Fifth Amendment, it would not be precluded from finding that meaning with respect to a **particular** interest never imagined by the framers — such as the right to access to an investigational drug. In so finding, however, the Court would be bound by the principles and parameters of life and liberty as envisioned by the original text of the framers, not as desired by contemporary judges.[2] Moreover, if the Court adhered to the authorial intent, it would abandon the Glucksberg non-textual

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[2] Thus, the Court would be precluded from defining "liberty," for example, in terms of recent events in Europe (*e.g.*, Lawrence v. Texas, 539 U.S. 558, 572-73, 576 (2003)), or changes in state law over the past 70 years (*id.* at 571-72).

tests[3] which, after all, are needed only because it has exchanged for the text, "**guideposts**" — that are admittedly "**scarce and open-ended**," the Court having entered into an "**unchartered area**" that risks substantive due process to be "subtly transformed into the **policy preferences** of the members of [the] Court." Glucksberg, 521 U.S. at 720 (emphasis added). By adhering to authorial intent, the Court would return to the chartered waters of the constitutional text which would, first of all, place a time constraint on the Court's search for the substantive meaning of the due process protection of life and liberty.

It is notable that, even though it posits that a claim of life or liberty right must be "deeply rooted in this Nation's history and tradition," the Glucksberg test does not specify any time frame. Taking advantage of this ambiguity, the *en banc* majority below made no distinction between events which preceded the insertion of the terms "life" and "liberty" in the Fifth Amendment when proposed in 1789 and ratified in 1791, and those events which followed that date. Instead, the court concluded that "our Nation has long expressed interest in drug regulation," citing to six state legislative measures in the 1700's and 1800's, and federal domestic regulation beginning in 1902 (following one restriction on imports in 1848). *See* Abigail Alliance, 2007 U.S. App. LEXIS 18688, at 22. However, only one of these events antedated the Fifth Amendment — a 1736 Virginia statute which addressed the problem of selling drugs in greater quantities than necessary or useful to the patient, certainly no authority for the conclusion drawn by the *en banc*

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[3] "[T]he Due Process Clause specially protects those fundamental rights and liberties which are, objectively, [i] 'deeply rooted in this Nation's history and tradition' and [ii] 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Id.*, 521 U.S. at 721.

majority. *Id.* at 71, n.4. Moreover, by examining the actions of legislative bodies, rather than the text of the constitution, the *en banc* majority looked to legislative acts to ascertain the meaning of "life" and "liberty," ignoring the fact the Due Process Clause is designed to limit the government, not empower it.

III. A Textual Understanding of the Fifth Amendment "Life" and "Liberty" Interest Supports a Person's Right to Choose His or Her Own Medical Care.

In Meyer v. Nebraska, this Court looked to the common law to define the meaning of "liberty" as it appears in the Due Process Clause of the Constitution. *Id.*, 262 U.S. at 399. Its examination of the common law, however, was not an indiscriminate one. Rather, it looked to "those privileges long **recognized** at common law as **essential** to the orderly pursuit of happiness by free men." *Id.* (emphasis added). Unstated by the Meyer Court, but well-established in the early history of the nation, the common law to which it referred was not the bundle of discretionary rules based upon the customs of men, but the obligatory rules that were "declaratory of, and ... in subordination to" "the law of nature and the law of revelation," as "expressly declared so to be by God Himself," as Sir William Blackstone had written in his Commentaries on the Laws of England. I W. Blackstone, Commentaries on the Laws of England 42 (U. Of Chi. facsimile ed. 1979) (hereinafter "Blackstone's Commentaries").

Originally published in England from 1765 to 1769, an American edition of 1,400 copies of Blackstone's Commentaries was published in Philadelphia between 1771-72 and quickly sold out, with a second edition published soon thereafter. These Commentaries were extant in the proper time frame, and thus, a primary source for understanding the

meaning of "life" and "liberty," as reflected in the Fifth Amendment text and the intent of its authors. Indeed, Librarian of Congress Emeritus Daniel J. Boorstin wrote that "Blackstone's work ... became the bible of American legal institutions." The Mysterious Science of the Law (1941), p. xv.

Both the panel opinion and the *en banc* dissent below cited Blackstone for the principles: (a) that "**personal security**" includes (i) "a person's legal and uninterrupted enjoyment of his life, his limbs, his body [and] his **health**," and (ii) "the preservation of a man's **health** from such practices as may prejudice or annoy it;" and (b) that the right to **self-defense** and the right to **self-preservation** are defined in these terms — "[f]or whatever is done by a man to save either life or member, is looked upon as done upon the highest necessity and compulsion." Abigail Alliance, 445 F.3d 470 (2006), at 480; Abigail Alliance, 2007 U.S. App. Lexis 18688, at 66 (emphasis added). As important as these descriptions of the laws of England are, they miss the **divine** context within which Blackstone discusses these rights, a context which richly informs an understanding of the terms "life" and "liberty" in the Fifth Amendment.

First, Blackstone notes that the law divides persons into two categories, one natural, "such as the God of Nature formed us," and the other "artificial ... such as created and devised by human laws...." I. Blackstone's Commentaries at 119. Blackstone then explains "[t]he rights of persons ... are ... of two sorts, absolute and relative. **Absolute**, which are such as appertain and belong to particular men, merely as individuals or single persons: **relative**, which are incident to them as members of society, and standing in various relations to each other." *Id.* at 119 (emphasis added). Absolute rights are "such as would belong to their persons merely in a **state of nature**...." *Id.* (emphasis added). "For the **principal aim of society** is to

protect individuals in the enjoyment of those absolute rights, which were vested in them by the **immutable laws of nature**.... [T]he first and **primary end of human laws** is to maintain and regulate these absolute rights of individuals," not to change them. *See id.* at 120 (emphasis added). "This natural liberty consists properly in a power of acting as one thinks fit, without any restraint or control, unless by the **law of nature**: being a right inherent in us by birth, and one of the **gifts of God** to man at his creation, when he endued him with the faculty of free will." *Id.* at 121 (emphasis added). "[E]very **wanton and causeless restraint** of the will of the subject, whether practiced by a monarch, a nobility, or a popular assembly, is a degree of tyranny." *Id.* at 122 (emphasis added). "[T]hat constitution ... is alone calculated to maintain civil liberty, which leaves the subject entire master of his own conduct, **except** in those points wherein the public good **requires** some direction or restraint." *Id.* (emphasis added).

Blackstone does not merely posit a theoretical state of nature as do certain "ethical writers" who use "human reason" to devise a "moral system" and then denominate it the "natural law." Blackstone's Commentaries (ed. William C. Jones, 1915, reprinted 1976) at 64. Rather, Blackstone identifies "natural law" as "only what, by the assistance of human reason, we imagine to be" the law of nature (Blackstone's Commentaries at 42).[4] The "law of nature" is, by contrast, "expressly declared so to be by God himself" (*id.*), having impressed it upon man at the time of creation according to His will, having "laid down

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[4] Even from a secular viewpoint, Hobbes asserts: "If the sovereign command a man, though justly condemned, to kill, wound, or maim himself; or not to resist those that assault him; or to abstain from the use of food, air, medicine, or any other thing, without which he cannot live; yet hath that man the liberty to disobey." Thomas Hobbes, *Leviathan* (Simon & Schuster, Inc., 1962), p. 164.

certain **immutable** laws of human nature...." *Id.* at 39-40 (emphasis added). "This **law of nature**, being co-eval with mankind and **dictated by God himself**, is of course superior in obligation to any other. It is binding over all the globe, in **all countries**, and **at all times**: no human laws are of any validity, if contrary to this...." *Id.* at 41 (emphasis added). "The doctrines thus delivered we call the revealed or divine law, and they are to **be found only in the holy scriptures**." *Id.* at 42 (emphasis added).

Fully consistent with Blackstone's divine foundation for the common law, America's Declaration of Independence lays the same foundation for the United States, namely, the "**Laws of Nature** and of **Nature's God**." (Emphasis added.) Additionally, and again fully consistent with Blackstone's views of the "immutability" of the laws of human nature as established by man's Maker, the Declaration asserts the inalienability of man's rights to "**Life, Liberty, and the pursuit of Happiness**," as endowed by their **Creator**. (Emphasis added.) Finally, and again fully consistent with Blackstone's view of the duty of governments to "protect" man's absolute" rights, the Declaration claims:

> That to **secure** these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed. [Emphasis added.]

After adopting a constitution for the nation, in part, to "secure the blessings of liberty," the people of the United States ratified a Bill of Rights, the fifth article of which is designed to protect the God-given rights to life, liberty and property of its inhabitants. 170 years later, Justice William O. Douglas observed that "the body of the Constitution as well as the Bill of Rights enshrined" the "principles" of the Declaration's commitment "that **the individual possesses rights**, conferred

by the Creator, **which government must respect**," "among [which] are Life, Liberty, and the pursuit of Happiness." McGowan v. Maryland, 366 U.S. 420, 561-62 (1961) (Douglas, J., dissenting) (emphasis added).

Unquestionably, the authors of the Due Process Clause of the Fifth Amendment[5] drew on this terminology of the Declaration to forge the Due Process Clause's protection of "life" and "liberty" as defined by God.[6] Thus, the meaning of those terms cannot be ascertained without reference to the common law, the rights of man, the role of the Creator, and the purposes of government set out in the nation's Charter, the Declaration of Independence[7] where the rights to life and liberty are "rights by nature [existing] prior to and independently of any political order." Dan Himmelfarb, "Note: The Constitutional Relevance of the Second Sentence of the Declaration of Independence,"

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[5] Of course, the Declaration's final God-given right identified as "pursuit of happiness" is replaced by "property" in the Fifth Amendment.

[6] The author of the Declaration had little use for government meddling in personal medical choice: "Was the government to prescribe to us our medicine and diet, our bodies would be in such keeping as our souls are now. Thus in France the emetic was once forbidden as a medicine, and the potatoe as an article of food." Thomas Jefferson, *Notes on the State of Virginia* (Harper & Row, 1964), p. 152 .

[7] Before appointment to this Court, Justice Thomas observed that: "the Constitution makes explicit reference to the Declaration of Independence in Article VII, stating that the Constitution is presented to the states for ratification by the Convention 'the Seventeenth Day of September in the Year of our Lord one-thousand seven-hundred and eighty-seven of the Independence of the United States of America the Twelfth....' The Constitution recognized that the Declaration "marks a *novus ordo seclorum*, a new order of the ages." Clarence Thomas, "An Afro-American Perspective: Toward a 'Plain Reading' of the Constitution — The Declaration of Independence in Constitutional Interpretation," 1987 How. L.J. 691 (1987), at 695.

100 Yale L.J. 169, 172 (October 1990).

IV. The Holy Scriptures Confirm a Common Law Right to Choose Medical Care to Preserve One's Life.

While rights of life and liberty are found in the common law, they are confirmed by the laws in the Holy Scriptures, which Blackstone asserts are "of infinitely more authority than what we generally call the natural law," in that they have been directly revealed by God to man "in compassion to the frailty, the imperfection, and the blindness of human reason...." I Blackstone's Commentaries at 41-42. Blackstone wrote that "upon these two foundations, the law of nature and the law of revelation, depend all human laws; that is to say, no human laws should be suffered to contradict these." (*Id.* at 42). Blackstone understood that the laws of men, if contrary to God's law, were of no "validity" at all. *Id.* at 41.

The question before this Court, then, is whether the FDA regulation that prohibits a terminally ill patient from access to a potentially life-saving drug may be justified as "necessary for the benefit of society," a matter of "indifference" to God, or whether that regulation conflicts with the revealed law of God protecting life and liberty. *Id.* at 42.

With respect to life, from the very first book of the Bible — the Book of Genesis — God is revealed as both **light** and **life**. He created light prior to creating the bearers of light, revealing that God (and not the sun or any heavenly bodies) is the source of all light. Genesis 1 also reveals that He is the source of all life, in that He created all plant, animal, and human life, and with respect to human life, God created man, male and female, in his image. As Blackstone put it, "[l]ife is the immediate gift of God, a right inherent by nature in every individual...." 1 Blackstone's Commentaries at 125. As God's image-bearer,

the Bible teaches the sanctity of human life, undergirding it by the commandment "Thou shalt not kill" (Exodus 20:13) and by the granting of authority to civil government to punish murder (Genesis 9:6), as defined by the law of Moses (Exodus 21:12-14). *See* IV Blackstone's Commentaries at 194. As the Author of all of human life, each human being has a duty before God to choose life, not death. *See, e.g.,* Psalm 139. *See also* IV Blackstone's Commentaries at 189 ("[N]o man hath a power to destroy life, but by commission from God, the author of it: and, as the suicide is guilty of a double offence; one spiritual, in invading the prerogative of the Almighty, and rushing into his immediate presence uncalled for; the other temporal, against the king, who hath an interest in the preservation of all his subjects....").

The New Testament confirms the Old, saying of Christ, that "In Him was life; and the life was the light of men. And the light shineth in darkness; and the darkness comprehended it not." John 1:4-5. The Creator's laws are therefore for the purpose of life, because He is life. James teaches us that sin brings forth death. James 1:15. This is also evidenced in the Old Testament. *See, e.g.,* Proverbs 10:27, 11:19, 12:28, 13:14, 19:16. All of God's commands are to preserve and enhance life and to save from death. James 1:21. Therefore, as Creator, His commands are set forth for mankind to give and sustain life.

With respect to **liberty**, the Book of Genesis teaches that man, created in the image of God, is endowed with an ability to choose right and wrong. *See* Genesis 3 and 4. From the beginning, God has exhorted men and women to choose life, not death. Genesis 2:16-17. Indeed, in His covenant with the nation of Israel, God so commanded the people: "I call heaven and earth to record this day against you, that I have set before you life and death, blessing and cursing: therefore choose life, that both thou and thy seed may live." Deuteronomy 30:19.

Again the New Testament bears witness to the Old in that James says that Christians will be judged by the "law of liberty" (James 2:12), referring to the New Covenant which includes all the teaching and commandments from God as written by the apostles. And, as James clearly teaches, obedience to God's commands prevents premature death that results from sin. *Cf.* James 1:13-27. Paul says, "For you, brethren, have been called to liberty; only do not use liberty as an opportunity for the flesh but through love serve one another. For all the law is fulfilled in one word, even in this: 'You shall love your neighbor as yourself.'" Galatians 5:13-14.

Romans 3:20 teaches that "by the law is the knowledge of sin" — that is, the law teaches us what is right and wrong, good and evil. *See also* Romans 7:6, *et seq.* In this context of Romans 13:1-10, Paul has given instruction concerning the role of human government, to "execute wrath upon him that doeth evil" and to commend that which is good. *See* Roman 13:3-4.

From these revealed principles from Holy Scriptures, it is understood that each human being has been endowed by the Creator with an unalienable "liberty" and right to make life and health enhancing medical choices that seek to preserve and prolong God-given life, and that governments are instituted among men only to preserve, and never to denigrate, such a right. These are the necessary elements which need to be studied in understanding the framers' authorial intent of "life" and "liberty" in the Fifth Amendment.

V. The Administrative Process by Which the FDA Limits Access of a Terminally Ill Patient Deprives the Patient of His Life and Liberty Without Due Process of Law.

As stated by the *en banc* majority, the Federal Food, Drug,

and Cosmetic Act "generally prohibits access to new drugs unless and until they have been approved by the Food and Drug Administration (FDA) [and] [g]aining approval can be a long process." Abigail Alliance, 2007 U.S. App. LEXIS 18688, p. 3. Not only is the process lengthy, but also it can only be initiated by "an experimental drug's sponsor" upon a showing that, after significant investigative efforts, "human testing is appropriate" to ascertain whether the new drug is "'safe for use and ... effective in use." *Id.* The clinical testing process, in turn, is open to relatively few human subjects, usually 20 to 80 in Phase I, several hundred in Phase II, and several hundred to several thousand in Phase III. *Id.* at pp. 4-5. No person is entitled as of right to have access to any drug at any one of the three trial phases. While a terminally ill patient need not "always await the results of the clinical testing process," such access is extremely limited, and within the complete discretion of the FDA. *Id.* at 6-7.

The FDA has not been and is not capable of fulfilling its grave responsibilities. The Commissioner of the FDA, Andrew Von Eschenbach, respondent in this case, requested that the Science Board (an Advisory Board to the Commissioner) form a subcommittee to conduct a study to "assess whether science and technology at the FDA can support current and future regulatory needs." FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology, November 2007 ("FDA Science"), p. 2.[8] This November 2007 report highlighted substantial weaknesses in the FDA's scientific organization structure, concluding that "the Agency ... is not positioned to meet current or emerging regulatory responsibilities." FDA Science, p. 2. In essence, the report demonstrates that, according to the FDA itself, its processes are

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[8] http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf

flawed. In essence, under the Federal Food, Drug, and Cosmetic Act, the administrative processes by which a person is afforded access to a potentially life-saving drug is made by the FDA, not on an individual basis, but upon generalized assessment of patient needs as balanced against a scientifically flawed assessment of likely benefits and harms.

According to the common law of England extant at the time of the nation's founding, the process due to a person seeking medical treatment was a **judicial** one, available to a person **after** making a decision to undergo such treatment by a licensed physician or surgeon. As Blackstone observed, "[i]njuries, affecting a man's *health*, ... by the neglect or unskillful management of his physician, surgeon, or apothecary" gave rise to a private cause of action. *See* III W. Blackstone's Commentaries at 122. Thus, at common law, a person's access to medical treatment was unencumbered by any **preventive** administrative process or other governmentally-enforced standards designed to prohibit access to unsafe, defective or corrupted drugs. *See* Abigail Alliance, 2007 U.S. App. LEXIS 18688, at 24, n.7. Indeed, not until the 1938 amendments to the Federal Food, Drug, and Cosmetic Act were "drug manufacturers" required to "provide proof that their products were safe **before** they could be marketed." *Id.* at 28. Prior to those amendments, the federal law followed the common law pattern, prohibiting the manufacture of any "'adulterated or misbranded'" drug. *See id.* at 28.

In its review of the American common law tradition, however, the *en banc* majority failed to acknowledge this distinction, having assumed that "our Nation's history of regulating the *safety* of drugs" had, from the beginning, included preventive measures designed against drugs that "have not been proven safe" to some government agency. *See id.* at 21-27. To the contrary, the 1938 amendments were strenuously

opposed "'on the ground that it would deprive the American people of the right of self-medication.'" *Id.* at 28. Indeed, the 1938 change-over, coupled with the 1962 amendments conferring upon the FDA power to "only approve drugs deemed effective for public use,"[9] "wrest[ed] life and death decisions that once were vested by the common law in patients and physicians,"[10] subject only to the judicial process, and transferred such decisions to the FDA, subject only to the administrative process.

As this Court observed 151 years ago, "Congress [is not] free to make any process 'due process' of law,' by its mere will." Murray v. Hoboken Land and Improvement Co., 59 U.S. (18 How.) 272, 276 (1856). Rather, the Fifth Amendment's Due Process Clause bound Congress to "those settled usages and modes of proceeding existing in the common and statute law of England, before the emigration of our ancestors.... *Id.* Such settled usage, as Blackstone observed, was "a right of every Englishman [to] apply[] to the courts of justice for redress of injuries." I Blackstone's Commentaries at 137. Blackstone's view was echoed by several early American legal authorities, most succinctly by St. George Tucker, who wrote that "[d]ue process of law must then be had before a judicial court, or a judicial magistrate." St. G. Tucker, View of the Constitution of the United States with Other Writings, p. 148 (Liberty Fund, Indianapolis: 1999).[11] Indeed, since the abolition of the English

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[9] *See id.* at 28.

[10] *See id.* at 60 (Rogers, J., dissenting).

[11] *See also* II J. Kent, Commentaries on American Law, Part IV, Lecture XXIV, pp. 1-8 (Claitor's Publ. Div., Baton Rouge: 1827); 2 J. Story, Commentaries on the Constitution, Book III, C. XXXVIII, p. 567 (5th ed. Little, Brown, Boston: 1891); and Kilbourn v. Thompson, 103 U.S. 168, 182 (1881).

Court of Star Chamber in 1641, it had been firmly established that common law rights were to be adjudicated according to "a system of justice administered by the courts instead of by the administrative agencies of the executive branch of government." *See* Sources of Our Liberties 132 (R. Perry and J. Cooper, eds., Rev. Edition, ABA Foundation: 1978). Thus, the Murray Court concluded that "Congress can[not] withdraw from judicial cognizance any matter which, **from its nature**, is the subject of a suit at the common law." Murray v. Hoboken Land and Improvement Co., 59 U.S. (18 How.) at 284 (emphasis added).

At common law, the patient's right of access to health care was, in its nature, an "absolute" right to life and liberty, arising out of the very nature of man, not a "relative" benefit, having been conferred to them as members of a civil society. *See* III W. Blackstone's Commentaries at 119-120. Since 1938, however, Congress has treated the use of drugs in medical treatment as if access to medical treatment by such drugs were a "relative" benefit conferred on mankind by the FDA, requiring the manufacturer of a drug to prove to the FDA by an administrative process that it was "safe" before a person was afforded access thereto for the preservation of the person's health. *See* Abigail Alliance, 2007 U.S. App. LEXIS 18688, at 27. Furthermore, under current law, a person may have access to a drug that the FDA has determined to be "safe" enough for substantial testing upon human beings, but individual access to such a drug is determined by an impersonal administrative process, as if an individual person's access to health care is, like the U.S. mails, a privilege conferred by the government, rather than an inalienable liberty with which every individual is endowed by "the great creator [which] cannot legally be disposed of or destroyed by any individual ... merely upon [his] own authority." *See* I W. Blackstone, Commentaries at 129. Indeed, as Blackstone has so ably argued, "no man shall be

forejudged of life or limb, contrary to the great charter of the law of the land [and] that no man shall be put to death, without being brought to answer by due process of law." *Id.* (emphasis added).

The administrative processes by which the FDA determines whether a drug is safe and effective operates to "forejudge" the life of a patient without the benefit of judicial process, contrary to the law of the land. In effect, the FDA impedes the patient from pursuing the preservation of his life without having to give an account for its decision in a judicial proceeding designed to protect the patient's common law right to preserve his life and his health.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully Submitted,

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December 13, 2007