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Commercial Markets Created by Abortion: Profiting from the Fetal Distribution Chain

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CONTENTS

INTRODUCTION

The abortion divide is commonly viewed as an ideological conflict. Does a woman's right to make reproductive choices eclipse the right to life of a developing fetus? Too often the rhetoric begins and ends at this level of discourse.

An ideology may be defined as "a system of collectively held normative and reputedly factual ideas and beliefs and attitudes, advocating and/or justifying a particular pattern of political and/or economic relationships, arrangements and conduct."[1] It is a wide-ranging shared belief system that can serve to motivate and justify and to provide the foundation for programs of political and social action. "Leaders of sociopolitical movements realize that there will inevitably be times when a movement's ideology will conflict with the experiences and moralities of their followers. At those moments, followers must reject their own consciences and blindly fall back on the accepted dogma."[2] This quotation characterizes the ideological divide surrounding abortion. It is today's most polarizing issue.

There is a particular cultural vision that provides motivation and justification for access to legal abortion by focusing on a woman's autonomy, privacy, equality and right to self-determination. Understanding this vision is fundamental to understanding the deep reluctance of the pro-choice community to abandon the status quo as it relates to abortion. By the same token, those who reject abortion do so based on an anthropology that embraces as central the individual human person, his dignity, intrinsic worth and right to life, regardless of stage of development or state of life. This vision of the person is irreconcilably at odds with the acceptance of abortion.

Today the abortion industry claims a unique place as an established structure of American society. It benefits from legal and governmental protections. Juridical cases upholding abortion rights indicate its relatively secure position in federal and state courts. Explanations as to why it has come to occupy this position vary. Perhaps it is the will of the majority, the sheer political strength of an ideological movement, or a postmodern vision of what

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[1] M. B. HAMILTON, "The Elements of the Concept of Ideology", *Political Studies* 35 (1987) 18-38.
[2] M. CRUTCHER, *Lime 5: Exploited by Choice*, Life Dynamics, Incorporated, Denton 1996, 205.

constitutes a "right" for the human person and a "good" for the society. Putting aside the ideological question for the moment, it appears that abortion-related businesses, silently springing up and maturing over the past forty years, could now be influencing the abortion debate. The reality of these businesses is not often part of the general public's knowledge or concern.

Is there a commercial case for preserving the abortion industry in its present form that transcends ideology? Are special interests driving the industry? How much power, if any, do financial considerations wield when weighed against societal norms, rules and laws that govern abortion? Does the public's ignorance of these factors contribute to maintaining the abortion culture as it exists today? If people understood these factors, might their ideas about abortion change? As commercial ventures, how much profit do the abortion industry and those industries dependent upon it generate---and to what interests? What extent does money, "the root of all evil," play in understanding the complex calculus of abortion?

As a practical matter, this paper cannot settle the question of whether abortion is predominantly an ideology or a commercial enterprise. To some degree, it is both. It will instead focus on industrial sectors whose origin and growth are a result of legalized abortion. The culture of abortion is multifaceted. Its influence has permeated countless segments of society. It has created new commercial markets and molded existing ones. While it fulfills the definition of an ideology, particularly in those who inhabit its two extreme positions, economic revelations that underlie the abortion industry may affect the thinking of those less resolved individuals inhabiting the more moderate center.

Little is widely known about the business aspects of the abortion industry that relate to its function of supplying electively-aborted fetuses to industries that exploit them for economic gain. An unintended consequence of the essentially unencumbered right to abortion has been the creation of a vast and lucrative market in fetal tissue, fetal organs and fetal parts.

This paper will attempt to follow the money trail in an effort to expose those special interests that contribute to abortion's control over the American culture and the American

economy. It will examine some industries connected with and profiteering from the abortion industry, some directly and some more remotely.

Chapter 1 will look at general foundational aspects of abortion. Chapter 2 delves into the social, commercial, political and juridical systems that make the abortion industry itself profitable. Chapter 3 examines the fetal parts industry, an industry that could not have developed without a legal and protected abortion structure. Chapter 4 follows fetal-tissue technology into the pharmaceutical industry. Chapter 5 reveals how fetal-tissue supply and demand shape the cosmetics industry. Finally, Chapter 6 analyzes the ethical implications of the practices taking place and why it is necessary to shine a light on these practices. The scope will generally be limited to the United States, except in cases involving worldwide markets.

Chapter 1

FOUNDATIONS OF ABORTION

Who profits from abortion? Abortion does not affect just one person. It impacts individuals, families, businesses and society at large. Thus, many people and entities can potentially be involved not only in abortion's choice and execution, but also in its aftermath---the disposition of the fetus.

1.1. Individual Impact

The terminated fetus would seem to profit least from abortion. There may be cases where he is spared a life of hunger and pain, suffering and sorrow; however, this is a decidedly nihilistic view of mankind. Not only does it discount the possibility of the experience of pain by the fetus during abortion, but it also avoids the larger question of the purpose and value of human life and existence in general. As a philosophical tenet, most would agree that it is better to be than not to be.

Whether the mother benefits from abortion has been the subject of considerable debate. The pro-choice community points to the relief experienced by the woman who escapes an undesirable situation, her crisis pregnancy. She is restored the ability to control her body and her future. The pro-life community cites a not insubstantial body of evidence that documents a woman's feelings of guilt and pain, as well as the physical and emotional distress that can accompany abortion.[3] Pro-choice advocates point out that the father, if he knows, may also experience relief on emotional and economic levels---often more so than the mother. But men too have been shown to suffer as a result of abortion and regret the loss of fatherhood. Some have voiced frustration at a legal system which gives the woman sole control over determining the fate of their child.[4]

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[3] V. THORNE, "Manifestations of Abortion's Aftermath in Women", in http://www.noparh.org [6-2-2009]. D. M. FERGUSSON - L. J. HARWOOD - J. M. BODIN, "Reactions to Abortion and Subsequent Mental Health", *The British Journal of Psychiatry* 195 (2009), 420-426.

[4] G. CONDON - D. HAZARD, *Fatherhood Aborted,* CareNet U.S.A. 2001, 31.

Compared with the volumes written about the post-abortive woman and the terminated fetus, remarkably little has been written about the third necessary participant in abortion---the abortionist. Doctors who have the training and vocational calling to perform the procedure are crucial to the abortion industry's ability to provide abortion access to women. Besides impacting the doctor, a facility's medical and administrative staff is affected by its proximity to abortion. The staff closely participates in that it counsels the women, prepares them for the operation, assists during surgery and recovery, and disposes of fetal remains.

In *Necessity and Sorrow*, pro-choice author Magda Denes chronicles her research evidencing the conflicts experienced by abortionists. One abortionist confessed, "As a physician, I'm trained to conserve life… I guess I feel guilty because according to the Hippocratic Oath[5] you're not supposed to do abortions."[6] But others are dedicated to the field. The Executive Director of the American College of Obstetricians and Gynecologists says, "By and large, [abortion doctors] are zealots who are strongly committed and who believe, in most instances correctly, that if they don't provide the service, no one will."[7]

While many doctors enter the field on ideological grounds or based on a belief that this area of medicine is underserved, abortion is also a lucrative business. Doctors can earn significantly more money performing abortions than they can by practicing other kinds of medicine. Although the chargeable fees and reimbursements available for a routine first-trimester abortion are generally low, the per-procedure fees are more than offset by the high volume of abortions that can be performed in a single day.[8] This is particularly true since many women below the poverty level, who might not otherwise be able to pay for an abortion, are subsidized through state Medicaid programs.

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[5]The Hippocratic Oath, as originally formulated in the latter half of the fourth century BC, contained the following prohibition: "I will not give a woman as pessary to cause an abortion."

[6]M. DENES, *In Necessity and Sorrow*, Basic Books, Incorporated, New York, 1976.

[7]W. H. PEARSE, M.D., American College of Obstetricians and Gynecologists, *New York Times* (8-1-1990).

[8] M. CRUTCHER, *Lime 5: Exploited*…, 189.

1.2. Socio-Economic Impact

An early argument advanced in favor of legal abortion was that it would contribute to the common good by solving prevailing social problems: child abuse, violence against women, single-parent households, poverty, etc. "Every child, a wanted child," was a popular slogan. However, these social ills would seem to remain notwithstanding the elimination of millions of presumably unwanted children. As to child abuse, studies indicate a reverse trend. A prior history of abortion has been shown to produce more child abuse, not less, in subsequent pregnancies.[9]

Some claim that one ideology underlying abortion is eugenic in nature.[10] Demographic data points to a disproportionate concentration of abortion facilities located in economically-disadvantaged black and ethnic neighborhoods. According to a 2008 study performed by the Alan Guttmacher Institute and reported in *The Washington Post*, "While the overall number of abortions has been falling in recent years, black and Hispanic women are making up a larger percentage of those receiving them. A large racial disparity was evident. Non-white women have the procedure at three to five times the rate of white women, the study found."[11] Currently, 36% of abortions performed in the U.S. are performed on African-American women, although black women of child-bearing age account for less than 13% of the population.[12]

Has the common good benefited from legal abortion? More women have taken the opportunity to complete their education, enter the workforce and leave the welfare roles. From an environmental standpoint, the collective "carbon footprint" may have been reduced and there may have been lower consumption of natural resources, both nationally and globally. But after

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[9] P. NEY - T. FUNG - A. R. WICHETT, "Relationship Between Induced Abortion and Child Abuse and Neglect: Four Studies", *Pre- and Perinatal Psychology Journal* 8/1 (1993), 43-63.

[10] Margaret Sanger founded the American Birth Control League in 1916, which eventually became Planned Parenthood. According to the Birth Control Federation of America's "Margaret Sanger Papers Project", she supervised the "Negro Project" which assembled clinical data to influence the adoption of clinics and contraceptive techniques primarily in the black communities of the South.

[11] UNITED PRESS INTERNATIONAL, INC., "Abortion Demographics Show Big Changes", *The Washington Post* (23-9-2008).

[12] C. H. CHILDRESS, JR., "The Dawning of a King's Dream" (2003), in http://www.blackgenocide.org/king.html [6-15-2009].

nearly fifty million legal U.S. abortions between 1973 and 2009, the data is inconclusive or dubious at best. Born in 1973, Caleb King, pastor at the Assembly of God's New Life Christian Center in Novato, California, lamented, "There is a growing sense in my generation that there are a lot of us missing, a lot of people with great potential." The logical question flowing from this is whether society has benefited from the largely unregulated, uncontrolled and uncontrollable abortion industry. This question has gone largely unasked and almost completely unanswered. The answer may be a function of economics.

Commerce, defined as "the exchange or buying and selling of goods, commodities or property,"[13] capitalizes on opportunity. It looks for utility in things that would otherwise be wasted and searches for innovative business ideas. Maximization of profits is the ultimate goal. Markets are created by exploiting supply and demand.[14] The choices the public exercises regarding the sort of markets it allows to be created are important. These choices create the kind of world in which we live. They define the ethics of a society.

When abortion became legal in the United States, no one anticipated that it would give rise to a tremendous market in fetal parts, tissues and cells. Campaigns advocating for a woman's right to choose never looked beyond the stated motivation---a desire for legal access to abortion---to the collective forces representing the creation of emerging markets.

Abortion became legal throughout the United States in 1973 with the *Roe v. Wade* Supreme Court decision. Until that time it was controlled by state law. Each of the fifty states regulated the practice to varying degrees. In *Roe v Wade,* the Justices ruled that abortion could not be restricted at all in the first trimester of pregnancy. Second-trimester abortion could be regulated only for reasons of the mother's health. During the third trimester, after viability, abortion could be prohibited except when necessary to preserve the mother's life or health.[15] Thus, the definition of "health" became all-important in determining the parameters of legal

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[13] Merriam-Webster's Dictionary of Law, Merriam-Webster, Inc. 1996.

[14]Supply and demand is an economic model based on price, utility and quantity in a market. It concludes that in a competitive market, price will function to equalize the quantity demanded by consumers and the quantity supplied by producers, resulting in an economic equilibrium of price and quantity.

[15] *Roe v. Wade*, 410 U.S. 113, 160-165 (1973).

abortion. A companion case, *Doe v. Bolton* (which the Court directed be read in conjunction with *Roe v. Wade*), defined maternal health so broadly as to effectively remove all significant legal barriers to abortion throughout pregnancy. Health was defined to include "all factors---physical, emotional, psychological, familial, and the woman's age---relevant to the well-being of the patient."[16] As a practical matter, if the existence of any of these health reasons could be demonstrated, abortion was legal during all nine months of pregnancy in all fifty states.

Other notable Supreme Court cases on abortion rights followed. *Planned Parenthood v. Casey* decided in 1992 upheld and more deeply entrenched in law the basic right to abortion, while expanding the ability of states to enact all but the most extreme restrictions on its access. *Stenberg v. Carhart* decided in 2000 overturned a Nebraska state ban on "partial-birth abortion" due to the lack of an exception for maternal health.[17] This unbroken line of cases has provided a continuous safe harbor for the abortion industry since *Roe*, allowing the growth of various satellite businesses that utilize the readily available fetal parts supplied by abortion.

"Where your treasure is, there also will your heart be."[18] Does the heart of the abortion industry in the United States really lie in the financial realm?

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[16] *Doe v. Bolton*, 410 U.S. 179, 192 (1973).

[17] Following the 8th Circuit Court's *Stenberg* v. *Carhart*, 530 U. S. 914 (1992), decision that Nebraska's "partial birth abortion" statute violated the Federal Constitution, as interpreted in *Planned Parenthood of Southeastern Pennsylvania* v. *Casey*, 505 U. S. 833 (2000), and *Roe* v. *Wade*, 410 U. S. 113 (1973), Congress passed the Partial-Birth Abortion Ban Act of 2003 to proscribe the dilation and extraction (D&X) method of ending fetal life used in the later stages of pregnancy.

[18] *Matthew 6:21.*

Chapter 2

THE ABORTION INDUSTRY

2.1. Industry Composition

The most direct financial gains from the abortion industry are realized by those physically providing abortions. Who are these providers and how many exist? In 2005, the most recent year for which complete statistics are available, there were 1,787 abortion providers in the United States. Just under half of these, or 887 clinics, offered RU486 chemical abortions.[19] Approximately 20% of abortion providers were members of the National Abortion Federation (NAF), according to information from its annual report. [20] Forty-five percent of abortion providers did business in independent free-standing clinics. Hospitals housed 34% of the providers and doctors' offices the remaining 21%. The greatest percent of abortions performed, 93%, were done in dedicated abortion clinics and other clinics; that is, those clinics where the majority of services provided are non-abortion services. Hospitals had a 5% share of the abortion market, with doctors' office registering only 2%.[21]

The largest existing network of affiliated abortion clinics is Planned Parenthood Federation of America (PPFA). It first performed abortions on July 2, 1970, the day after abortion became legal in New York state. By 1984, its clinics performed 5.5% of all U.S.

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[19]RU486 is a chemical abortion drug regime consisting of mifepristone or methotrexate and misoprostol. It was approved by the U.S. Food and Drug Administration September 2000 for abortions up to 49 days. Manufactured in China, it is distributed in the U.S. by Danco Laboratories, LLC. Mifepristone blocks progesterone, causing the uterine lining to thin and detach; methotrexate stops cell division, so is toxic to trophoblast tissue; misoprostol causes uterine contractions that expel the embryo and placental tissue. F. H. STEWART - E. S. WELLS - S. K. FLINN - T. A. WEITZ, "Early Medical Abortion: Issues for Practice", University of California at San Francisco, Center for Reproductive Health Research and Policy, San Francisco 2001, 20.

[20]The National Abortion Federation is a professional organization of abortion providers in the U.S. and Canada. Members include health care professionals at clinics, doctors' offices and hospitals (375 U.S. and 25 Canadian members), according to its website at http://www.prochoice.org. Some Planned Parenthood affiliates are included among member provider clinics.

[21] R. K. JONES - M. R. S. ZOLNA - S. K. HENSHAW - L. B. FINER, "Abortion in the United States: Incidence and Access to Services: 2005", *Perspectives on Sexual and Reproductive Health* 40/1 (2008), 6-13.

abortions, by 1997, 12%, and by 2004, just under 20%.[22] By 2008, that percentage was approaching 25%. Thus, its market share has increased steadily. The great majority of non-PPFA abortions are performed at independent clinics specializing in abortions, followed by more broad-based independent clinics.

In Table 1, PPFA's percentage of the abortion market is translated into number of abortions performed and estimated clinic income (in millions of dollars) generated by the abortions. The table covers the most recent five calendar years available.

Table 1

	2003	2004	2005	2006	2007
Number abortions	245,092	255,015	264,943	289,750	305,310
Income *(in millions)*	$ 88.2	$ 94.4	$ 100.7	$ 113.0	$ 122.1

Number of abortions was derived from published annual reports of PPFA and includes all of its affiliates. Estimated income was computed by multiplying the number of abortions performed by the estimated cost of a first-term abortion.

The typical average cost of a first-trimester abortion is from $300 to $500. A second-trimester abortion can range from $1,000 to over $1,500. More complicated third-trimester abortions can cost up to several thousand dollars. Nearly 90% of abortions are performed during the twelve weeks of the first trimester.[23] To the extent that some abortions included in Table 1 were performed in the second or third terms at correspondingly higher costs, income shown in the table is conservative.

2.2. Case Study

Planned Parenthood Federation of America, founded in 1916, and its overseas affiliate, International Planned Parenthood Federation, founded in 1952, represent the largest and most

[22] LIFE DECISIONS INTERNATIONAL, "Planned Parenthood Budget Up", *The Caleb Report* 7/8 (2007), 5.

[23] R. K. JONES - M. R. S. ZOLNA - S. K. HENSHAW - L. B. FINER, "Abortion in the…", 14-16.

efficiently-organized providers of abortion in the U.S. and worldwide. These non-profit organizations enjoy considerable economic and political power. Thus PPFA is central to any study of how a special interest is able to profit from the abortion industry and become a significant force in American society.

PPFA presents a comprehensive case study on how business evolves to capitalize on changes in the law and the prevailing culture. Another factor that makes it a good candidate for study is the availability of extensive public information for analysis. Each year, PPFA publishes an annual report[24] that offers complete financial information. Much of that information is attested to by independent certified public accountants. The financial activity of its U.S. operations is corroborated by tax-exempt income tax returns required to be filed annually with the Internal Revenue Service, a branch of the U.S. Department of the Treasury.[25] These tax returns are filed by the corporate officers under penalty of perjury and are open to public inspection by law.

Before examining statistical information, it is important to be aware of some key facts about abortion-related statistics. The Alan Guttmacher Institute, an affiliate of PPFA, is perhaps the *only* source of available, and arguably reliable, statistical data on abortion.[26] Guttmacher compiles more abortion-related data than any other U.S. source, including the federal government agency's Center for Disease Control and Prevention (CDC). To compile its abortion statistics, the CDC relies on submissions from state departments of health. State reporting requirements vary widely. The completeness of reporting compliance by providers to their respective state departments of health also varies. Some states---California, for example---do not collect or report abortion data at all.[27] Since California, the most populous state, is estimated to perform 20% of U.S. abortions, the CDC inevitably has significant gaps in its statistical data.

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[24]An annual report is a comprehensive report on a company's activities during its fiscal year and is intended to give shareholders and other interested parties information about the company's activities and financial performance. Most jurisdictions require public companies to prepare and disclose annual reports.

[25] Form 990, Return of Organization Exempt from Income Tax, is required to be filed annually by nonprofit organizations exempt from income tax under Section 501[c] of the Internal Revenue Code.

[26] Guttmacher Institute Annual Reports, 2007 and 2008.

[27]Department of Health and Human Services, Center for Disease Control and Prevention, Abortion Surveillance--United States 2000, 52/12 (2003), 1-32.

According to its annual report, Guttmacher receives substantial government funding to carry out this data-collection function. In 2007 and 2008, the Institute received government grants and contracts of $1.9 million and $1.2 million, respectively.[28] To accumulate statistical data, Guttmacher surveys nationally-representative samples of women who obtain abortions in the U.S. It conducts a periodic census of all known abortion providers and gathers information directly from them. Guttmacher is an affiliate of PPFA so access to confidential internal information regarding the activities of PPFA is virtually certain. The disadvantage of this arrangement is the lack of independence between Guttmacher as researcher and PPFA as the organization it putatively reports on. To illustrate, PPFA's 2007 tax return shows a $350,000 grant to the Guttmacher Institute. Economically self-serving reasons to shade or manipulate data thus undeniably exist, but no other comprehensive statistical sources are reasonably available.

2.2.1. Planned Parenthood Business Operations

In terms of number of existing abortion facilities, gross revenues generated, and profitability, PPFA leads the abortion industry by a substantial margin. For fiscal year ended June 30, 2008, PPFA boasted 115 affiliates with 844 health centers in all fifty states. Its gross revenues (defined as gross receipts before the deduction of expenses) for that fiscal year amounted to $1.038 billion. Net profits (excess of income over expenses) were $85 million.[29]

The gross revenue of Planned Parenthood Federation of America derives from three main sources: (1) health care income from clinic operations; (2) contributions and bequests; and (3) government grants and contracts. The less substantial "other income" category includes dividends, interest, gains or losses on sales of assets, rental income, sales of merchandise

[28] The percentage of support Guttmacher Institute received from government grants and contracts was 15% in 2007 and 10% in 2008. The most significant source of support received is from private foundation grants, which represented 70% of gross receipts in 2007 and 81% in 2008. More than half of these grants are restricted by donors for designated purposes or studies.

[29] Planned Parenthood Federation of America Annual Report for fiscal year ended June 30, 2008. National organization figures include the operations of Planned Parenthood Action Fund, Inc., which engages in lobbying activities through its Political Action Committee and its segregated fund, Planned Parenthood Votes. The operations of 115 affiliates are also included. Affiliates are independent corporations that operate local Planned Parenthood clinics. Each U.S. affiliate is a member of Planned Parenthood Federation of America.

inventory, membership dues, and income from special events. It also includes income from its affiliate, the Guttmacher Institute. Although exact percentages vary from year to year, for practical purposes it may be said that each of these three main revenue sources provides roughly one-third of PPFA's annual gross revenue. Table 2 provides detail on these revenue sources for its five most recent fiscal years (beginning July 1 and ending June 30).

Table 2 (in millions)

Fiscal year	03-04	04-05	05-06	06-07	07-08
Clinic income	$306.2	$346.8	$345.1	$356.9	$374.7
Government	$265.2	$272.7	$305.3	$336.7	$349.6
Contributions	$191.0	$215.8	$212.2	$258.7	$244.9
Other income	$ 47.6	$ 46.7	$ 40.2	$ 65.6	$ 68.8
Totals	$810.0	$882.0	$902.8	$1,017.9	$1,038.0

Category one, clinic income, contributes the greatest revenue to Planned Parenthood's bottom line. A comparison of income from abortions, as shown in Table 1, with total clinic income, as shown in Table 2, (after adjustment for calendar vs. fiscal year differences) indicates that abortions generate approximately one-third of clinic income. A former PPFA director confirmed to WorldNetDaily news service that abortion represents the most lucrative part of clinic operations.[30]

The other two-thirds of clinic income is generated through compensation for services involving contraception, sterilization, pregnancy testing, HIV and sexually-transmitted disease testing, cancer screening and a growing RU486 chemical abortion business.

Approximately 5,000 chemical abortions using RU486 were performed in the U.S. when this drug regime received government approval and went on the market in late 2000. That number rose to 55,000 in 2001, its first full year of use. In 2004, 140,000 women aborted using RU486, and in 2007, an estimated 158,000. RU486 is purported to be used in about 14% of all

[30] S. ERTELT, "Planned Parenthood Director who Quit was Pressured to Meet Abortion Quotas", *LifeNews.com* 11/5 (2009) in http://www.lifenews.com/state4548.html [7-11-2009].

abortions and 21% of abortions taking place in the first nine weeks gestation. The cost of a RU486 abortion is comparable to that of a first-trimester surgical abortion when follow-up visits are included.[31]

Government grants and contracts account for the second category of revenue noted in Table 2. Increasingly larger amounts are being obtained from various government programs each year. Almost $350 million was received in fiscal year 2007-2008. The money derives from several sources, but ultimately comes from taxpayer-funded subsidies. A portion of the governmental funding is from states and localities, particularly abortion-liberal states, like California and New York. The greater part, however, comes from two federal government programs---Title X and Medicare Waivers.

Title X of the Public Health Services Act represents a bipartisan measure passed by Congress in 1970 as a way to prevent population explosion in the U.S. It accomplished its objective by distributing free contraceptives to low-income families. Although Title X officially expired in 1985, Congress continues to appropriate money for the program through regulations issued by the Department of Health and Human Services. Planned Parenthood affiliates are major beneficiaries of this program.

The other federal program channeling at least $61 million per year to Planned Parenthood is known as Medicare Waivers. The program began in 1993, when the Department of Health and Human Services decided to waive---for purposes of receiving free contraceptives---its usual income limits for qualifying for Medicaid[32] benefits. Medicaid, unlike Title X, is an open-ended entitlement program so it is not dependent on Congressional appropriations for funding.[33]

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[31] L. B. FINER - J. WEI, "Effect of Mifepristone on Abortion Access in the United States", *Obstetrics & Gynecology* 9/12 (2009).

[32]Medicaid was founded in 1965 as Title XIX of the Social Security Act. It is a U.S. health program for eligible low-income individuals and families that is jointly funded by the states and federal government and managed by the states.

[33]C. ALLEN, "Planned Parenthood's Unseemly Empire: The Billion-Dollar Non-Profit", *The Weekly Standard* 13/6 (2007), 10.

The third main component of PPFA revenue is contributions, gifts, grants and bequests. It is generated through donations from individuals, corporations and large private family foundations, like the John D. Rockefeller and Bill and Melinda Gates Family Foundations. Since PPFA qualifies as a tax-exempt charity, tax laws are favorable to donors, allowing them a tax deduction against their income for amounts contributed.[34] For private foundations, making grants to public tax-exempt charities is statutorily encouraged and not restricted within certain boundaries.[35]

2.2.2. Clinical Trials

An interesting aspect of Planned Parenthood's revenue sources discussed above, and not readily discernible, is its involvement in clinical trials. Funded by a broad array of government agencies, universities, private foundations and pharmaceutical companies, twenty-eight PPFA affiliates have participated in thirty-three clinical trials over the past decade. Planned Parenthood not only augments its income through the trials, but also enhances its professional identity by strengthening its university, government and industry profile. Many of the trials carried out included young teens. A number focused on the African-American and Hispanic communities.[36]

Clinical trials conducted by the NIH and its pediatric branch, the National Institute of Child Health and Human Development, centered chiefly on birth control and emergency contraception; i.e.; contraceptive choice, long-term contraceptive use, hormonal contraceptives, condom use in high-risk women, and increasing emergency contraceptive use among fourteen to twenty-four year olds.[37]

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[34] INTERNAL REVENUE CODE (IRC) Section 170[c] allows a charitable contribution deduction to a corporation or trust organized in the U.S. and operated exclusively for religious, charitable, scientific, literary or educational purposes…or for the prevention of cruelty to children or animals. The organization must not be disqualified from exemption by IRC Section 501[c]3 for attempting to influence legislation.

[35] Charitable organizations are classified as either public charities or private foundations, depending upon their sources of support. Generally, public charities have broad public support, while private foundations are typically supported by one individual or family.

[36] J. SEDLAK, "A Review of Planned Parenthood Clinical Trials", *Special Report* (2009) in http://www.ss.all.org/pdfs/2009/stop_2009ppclinicaltrials.pdf, 1 [10-20-2009].

[37] Cf. *Ibid.*, 2.

Pharmaceutical company participation was common in contraceptive studies involving oral drugs, injections and device-related methods.[38] Merck, along with Emory University, conducted a clinical trial with Planned Parenthood Georgia designed to increase the use of its Gardasil Human Papillomavirus (HPV) injections. Bayer, along with the American College of Obstetricians and Gynecologists and Virginia Commonwealth University, joined the Virginia League of Planned Parenthood to study using NuvaRing, a vaginally-inserted birth control ring, in adolescents. Pfizer, along with the University of North Carolina, collaborated with PPFA in a trial training women to either self-administer Depo-Provera, a contraceptive injection, or to have the injection administered at a pharmacy. HRA Pharma is currently conducting trials at fifteen Planned Parenthood clinics on the safety and efficacy of Ella, a new emergency contraceptive designed to prevent pregnancy if taken three to five days after unprotected sex. [39]

These contraceptive trials gave way to a number of clinical trails involving medical abortion techniques. Trials are under way seeking possible variations in FDA-approved methods of administering mifepristone, misoprostol, methotrexate and other drugs that cause chemical abortions. Organizations funding these studies include Gynuity Health Projects (a research and technical assistance group promoting medical abortions worldwide), the Society for Family Planning and the David and Lucille Packard Foundation.

The amount of profit, if any, inuring to PPFA by virtue of its participation in clinical trials is unknown, as it is not separately stated for accounting purposes. However, the wealth of marketing information gleaned from these studies is likely to be of even greater value. In addition to being merely an abortion provider, PPFA is closely involved in researching and developing new contraceptives and more efficient abortion techniques. Thirty percent of its clinical trials included teens, age thirteen to eighteen. Attracting teenagers to contraceptive use is a component of the abortion industry's business plan, as is offering abortion as a remedy for failed birth control. According to a former Texas Planned Parenthood director, "The money was not in family planning or prevention, but in abortion." When struggling under the weight of a

[38]These contraceptive methods can have an abortifacient rather than a preventative effect in that they prevent the fertilized ovum from implanting in the lining of the uterus, thus destroying the zygote.

[39]Cf. J. SEDLAK, "A Review of Planned…", 2-4.

tough economy, its business model changed from one that pushed prevention to one that focused on abortion.[40]

2.3. Political Landscape

2.3.1. Federal Framework

When analyzing the political environment, it must be stressed that money is inseparable from politics, for good or for ill. A complex network of laws has been enacted to regulate political expenditures and lobbying in the U.S.[41] The laws attempt to guard against abuses, while preserving First Amendment Rights, particularly the right to free speech. Regulations were promulgated to establish who is eligible to lobby and what dollar limitations apply. Registration and reporting are required by entities making politically-motivated expenditures.

For reporting purposes, the U.S. Department of Treasury, through Internal Revenue Service Regulations, distinguishes between two categories of lobbying: direct and grassroots. Different regulations and contribution limits apply to each category. Direct lobbying is defined as "participation or intervention in any political campaign, on behalf of, or in opposition to, any candidate for public office."[42] In contrast, grassroots lobbying attempts to influence the general public on legislative or policy matters; it is issue-oriented rather than candidate-oriented. To understand the amount of influence PPFA has on the political system, it is essential to look at the financial magnitude of both its direct lobbying expenditures for candidates and its grassroots lobbying efforts related to issues.

Frequently, an organization established as a charity wishes to pursue multiple goals, including charitable outreach and education plus legislative and political advocacy. Structure becomes all-important to avoid running afoul of political expenditure and lobbying laws. This

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[40] Cf. J. HOFT, "Planned Parenthood Leader Resigns after Watching Abortion Ultrasound", in www.http://gatewaypundit.firstthings.com/2009/11/planned-parenthood-leader-resigns-after-watching-abortion-ultrasound/ [11-4-2009].

[41] Applicable laws include, but are not limited to, the Internal Revenue Code, Lobbying Disclosure Act, Federal Campaign Finance Law, Federal Election Campaign Law.

[42] INTERNAL REVENUE CODE Section 501[h]; Regulation Section 1.501[h]-1.

can result in monetary penalties and potential loss of tax-exempt status. The necessary structure can require a complex network of legally separate but affiliated entities under common control, but with differing stated purposes.

2.3.2. Planned Parenthood Structure

Planned Parenthood accomplished this objective by including in its overall structure four separate legal entities:[43] (1) Planned Parenthood Federation of America is a tax-exempt Internal Revenue Code (IRC) Section 501[c]3 charitable organization prohibited from engaging in political activities or substantial lobbying activities; (2) Planned Parenthood Action Fund is a tax-exempt IRC Section 501[c]4 social welfare organization that may engage in political activities, as long as these activities do not become its primary purpose; (3) Planned Parenthood Votes is a tax-exempt IRC Section 527 political organization that raises money either for issue advocacy or to influence the nomination or election of candidates; and (4) Planned Parenthood Political Action Committee (PAC) is a political committee that raises and spends money for the express purpose of electing or defeating candidates.[44]

Significant amounts of money are expended by Planned Parenthood for political purposes. It is extraordinarily difficult to determine which organization makes which expenditure. This lack of transparency is helpful in staying ahead of the political watch-dogs. Susanne Martinez, Planned Parenthood's Vice-President for Public Policy, wrote in a letter-to-the-editor that "Planned Parenthood's 501[c]4 group, its political action committee (PAC), and its 527 organization collectively spent more than $9 million during the 2000 elections." She did not, however, offer a breakdown of spending by individual affiliate.[45]

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[43] PUBLIC CITIZEN, "The New Stealth PAC's" (2008), in http://www.stealthpacs.org/profile.crm?print=print&org_id=2835 [7-24-2008].

[44] OPEN SECRETS.ORG CENTER FOR RESPONSIVE POLITICS, "Types of Advocacy Groups" (2009), in http://www.opensecrets.org/527s/types.php [7-29-2009].

[45] S. MARTINEZ, "Planning to Spend Big", *Roll Call* (5-15-2008), Letters to the editor.

2.3.3. Grassroots Lobbying

The blueprint for legislative advocacy issues opposed by PPFA can be found in the 1992 Supreme Court case *Planned Parenthood v. Casey*, which upheld the right to abortion while expanding the ability of states to regulate it. At issue in *Casey* were five provisions of the Pennsylvania Abortion Control Act of 1982. First, a woman seeking an abortion was required to give her informed consent prior to the procedure. Second, she was required to be provided with information about the fetus's development and abortion's health risks, along with counseling about abortion alternatives, at least 24 hours before performance of the abortion. Third, the law mandated the informed consent of one parent for a minor to obtain an abortion, allowing for a judicial bypass procedure when necessary. Fourth, a married woman seeking an abortion was required to sign a statement indicating that her husband had been notified of her abortion. Fifth, the law imposed certain reporting requirements on facilities providing abortion services. The Supreme Court only struck down the husband notification provision. All other provisions were deemed not to place an "undue burden" on a woman's access to abortion. "Undue burden" was defined as "a substantial obstacle in the path of a woman seeking the abortion of a nonviable fetus." [46]

PPFA, along with other abortion-rights advocacy groups, has a long history of opposing any restriction on abortion. The rationale is that any constraint on a woman's right or access to abortion systematically undermines the protections of *Roe v. Wade*. Proposed federal and state laws and initiatives that attempt to place any limitation on unfettered access to abortion have been vigorously fought. Both grassroots lobbying efforts and infusion of significant financial resources into legislative campaigns are employed to achieve this aim. Ballot initiatives containing restrictions proven to reduce the number of abortions are often defeated at the polls through PPFA's effective and costly campaigns. From the evidence, abortion reduction is not a goal of abortion providers. Abortion is a business and businesses are not in favor of legal restrictions leading to a loss of revenue.

[46] *Planned Parenthood of Southeastern Pa.* v. *Casey*, 505 U.S. 833 (1992).

One of the key issues in *Casey* confronted both at the federal level and in virtually every state, is parental involvement in the abortion of a minor. More than half the states have laws that mandate parental consent or notification before an abortion can be performed on an unemancipated minor. However, these laws are often circumvented when minors are transported across state lines to states that do not require parental involvement. Congress has tried to prohibit this practice and protect parental rights. The U.S. House of Representatives passed legislation four times between 1998 and 2005 to make it a federal offense to transport a minor across state lines for an abortion, without fulfilling the parental involvement requirements in effect in the minor's home state. Similar legislation was passed in the U.S. Senate in 2006. It was procedurally blocked by the Senate Democratic leadership, consistent recipients of PPFA's campaign contributions and targets of its lobbying efforts. None of these bills passed into law.

At the forefront of the fight against the Senate's Child Custody Protection Act and its House of Representatives' counterpart, the Child Interstate Abortion Notification Act, was the abortion lobby. It was led by the National Abortion Federation, NARAL Pro-Choice America, Planned Parenthood Federation of America and The Alan Guttmacher Institute.[47] One commentator expresses the dilemma that faces abortion providers this way:

> "If abortion advocates support reducing teen pregnancies, as they often claim, then why are they so harsh on a law which has been proven to reduce teen pregnancies? Perhaps it is because, according to Planned Parenthood's own statistics, mandatory parental involvement provisions result in a 24% to 85% reduction in teen caseloads at family planning clinics. (*Issues in Brief 4:3, March 1994, Alan Guttmacher Institute*) This reduction in caseload creates a reduction in cash flow for Planned Parenthood. Is it any wonder they dislike parental consent and notification laws?"[48]

At the state government level, thirty-seven of fifty states had parental involvement laws on their books at June 15, 2006. These were passed either by state legislatures or voters. Planned Parenthood affiliates brought suit in fourteen of these states to enjoin or overturn the

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[47] AMERICAN CIVIL LIBERTIES UNION, "Coalition Sign on Letter Expressing Opposition to the Child Custody Protection Act" (2004), in http://www.aclu.org/reproductiverights/abortion/12586leg30040601.html [7-30-2009].

[48] C.C. GARGARO, "Protecting the Rights of Parents and Young Women--in Defense of the Child Custody Protection Act", *The South Jersey Courier Post* (7-12-1998).

statutes. Other abortion businesses sued in six other states to prevent the laws from going into effect.[49] The challenges met with varying degrees of success in different states.

In California, three parental notification initiatives[50] were placed before voters during the past three election cycles. PPFA was consistently the largest funder of efforts to defeat the initiatives. Campaign strategies included the effective use of campaign literature, well-timed television and print advertisements, editorials and news stories, as well as direct-calling campaigns. Although opinion polls consistently showed overwhelming public support for parental notification (from 70% to 80%), all three initiatives narrowly failed following massive television ad campaigns by Planned Parenthood in the weeks preceding election day.

According to state campaign reporting-requirement disclosures, Planned Parenthood operations from across the nation spent approximately $5.5 million to defeat California's 2005 parental notification initiative. They spent $6.5 million against the 2006 initiative. A record-breaking $10 million went towards defeating the 2008 measure.[51] This influx of funds caused many to question whether state elections are being hijacked by out-of-state interest groups.[52]

2.3.4. Direct Lobbying

Which political candidates does PPFA support financially and ideologically? A comparison of the Democratic and Republican Party Platforms with respect to abortion answers the question. The Democratic Party Platform states, "Because we believe in the privacy and equality of women, we stand proudly for a woman's right to choose, consistent with *Roe v. Wade*. We believe it is a constitutional liberty." The Republican Party Platform states, "We say

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[49]NATIONAL RIGHT TO LIFE COMMITTEE, INC., "Parental Involvement Statutes-June 15, 2006" (2006), in http://www.nrlc.org/federal/CCPA/Index.html [7-30-2009].

[50]In an effort to give Californians a voice in state government, the California Constitution grants voters a right to engage in an initiative process to amend their constitution, adopt a state statute, overturn legislation passed by the state legislature and recall politicians at the state and local level. The initiative process is generally believed to benefit grassroots movements.

[51]CALIFORNIA CATHOLIC DAILY, "Undue Burden on Reform-Minded Californians" (2009), in http://calcatholic.web141.discountasp.net/news/newsArticle.aspx?id=4c430d5a-5a7c-48d9-8ad5-c1622a66f1ef [10-15-2009].

[52]Cf. W.F. JASPER, *"California's Prop 4: Abortion and Parental Notification"* (2008), in *http://www.thenewamerican.com/index.php/culture/family/371?tmpl=component&print=1 [7-30-2009]*.

the unborn child has a fundamental right to life. We support a human life amendment to the Constitution and we endorse legislation that the Fourteenth Amendment's protections apply to unborn children. We oppose abortion."

The logical inference, that the abortion industry overwhelmingly supports Democratic Party candidates, is supported by statistical data compiled by the Center for Responsive Politics. This organization tracks long-term political contribution trends by industry from information reported to the Federal Election Commission. During the 1990 through 2008 election cycles, the abortion industry made political contributions of $15.76 million. Of this amount, $12.61 million, or 80%, went to abortion-supportive Democrats running for office. The abortion industry was included in the top 80 industries contributing to the Democratic Party in each of these years, ranking 74th (on average) in total giving.

A review of the past several election cycles indicates that Planned Parenthood affiliates ranked in the top 50 abortion-industry political spenders.[53] PPFA is a potential source of considerable campaign contributions. This accounts for much of the power it exercises in the political arena. It also sheds light on the reasons why candidates and potential candidates would seek to establish and maintain a favorable working relationship with PPFA. That is, unless severe ideological differences made it impossible.

Congressional loyalty to this special interest group was demonstrated on July 29, 2009, when the Pence Amendment to defund Planned Parenthood was voted down in the U.S. House of Representatives primarily along party lines. The amendment to the Health and Human Services Appropriations Bill stated, "None of the funds made available under this Act shall be available to Planned Parenthood for any purpose under Title X of the Public Health Services Act." The reasons for introduction of the amendment were articulated by Republican Representative Chris Smith of New Jersey. He spoke in favor of its passage:

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[53] OPEN SECRETS.ORG CENTER FOR RESPONSIVE POLITICS, "Abortion Policy/Pro-Choice: Long-Term Contribution Trends" (2008), in http://www.opensecrets.org/industries/indus.php?ind=Q15 [5-25-2008].

> "Planned Parenthood has caused a staggering loss of children's lives. The organization aggressively lobbies and litigates against every modest restriction proven to significantly reduce abortions and has even opposed bans on partial-birth abortions… Planned Parenthood lobbies and litigates against prohibitions on taxpayer funding of abortion even though Planned Parenthood's own research shows that funding bans reduce abortion by 20 to 35 percent."[54]

As a practical matter, government funds awarded to PPFA for a specific restricted purpose----Title X spending, for example---results in available non-restricted funds being freed up for other elective purposes. This allows monies derived from any non-restricted source to support and enhance the abortion segment of its business, at the discretion of its directors. It is ironic that, in more than a few instances, the government has indirectly provided funds to PPFA to enable it to litigate federal cases restricting abortion; i.e.; cases requiring parental notification or banning partial-birth abortion. Thus, the government finds itself in the curious position of funding its own opposition in lawsuits of the type referred to above by Representative Smith.

"A house divided against itself cannot stand," warned the great slave emancipator, Abraham Lincoln.[55] The people and the government of the United States appear to be as divided on the question of abortion today as they once were on slavery.

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[54]CATHOLIC NEWS AGENCY, "U.S. House Votes Down Pence Amendment Intended to Defund Planned Parenthood", (2009), in http://www.catholicnewsagency.com/utilities/myprint/print.php [7-29-2009].

[55]In his Senate nomination acceptance speech of June 15, 1858, Abraham Lincoln quoted *Matthew 12:25*, in reference to the division of the country between slave and free states.

Chapter 3

THE FETAL TISSUE INDUSTRY

That a fetal tissue industry exists might surprise many people. Few questions are asked about what happens to the millions of fetuses that are by-products of abortion. In general, the public would rather not know the answers to these practical questions. Instead, assumptions are made or the aftermath of abortion is not consciously considered. The abortive mothers in particular are not the ones asking what becomes of the fetal remains. They understandably want to walk away from their experience quickly and quietly. Realistically, informed consent about the disposition of the fetus has little significance. Legal documents required to be signed before the abortion procedure takes place are frequently signed without understanding, under stress or even under duress. Consent may not always be free and informed.

Simply defined, fetal tissue is tissue taken from a human fetus. It includes the fetus in its entirety or individual fetal parts: i.e.; blood, bone morrow, organs, brain, spinal cord, eyes, arms, legs, etc. More recent scientific advancements have expanded the scope and usage of fetal tissue to include the cells of the embryo---the fetus in its earliest stage. Fetal tissue can be obtained ethically from ectopic pregnancies or spontaneous abortion (miscarriage), but the most available and functional source is induced abortion. Its uses include research, experimentation and product development.

Although disposition of fetal remains can take several forms, this chapter will specifically treat the acquisition and utilization of fetal tissue for research and development. To the extent the bodies are otherwise disposed of, the law requires that they be treated as medical waste and be either buried or incinerated. However, the practice of accepting fetuses for incineration is not the industry norm. Stericycle, the largest medical waste disposal company in the country, refuses to dispose of fetal remains due to a clause in their drivers' labor contract that allows the drivers to refuse to accept fetal waste. Typically, cremation of the remains takes place or they are released into the sewage system.[56]

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[56]Cf. M. GARCIA, "What do they do with them?", *San Francisco Faith* (1-6-2001).

Several factors make fetal tissue a preferred source of transplant material, including its potential for growth, its ability to differentiate into other types of cells, and its ability to integrate into a transplant recipient with decreased possibility of rejection. These factors are the same ones cited today in identifying the unique advantages of human embryonic stem cells in research and potential medical treatments.

3.1. Legal History

American researchers have engaged in fetal tissue research since the 1930's. Fetal tissue transplants first became successful in 1968. These transplants were thought to hold particular promise for Parkinson's disease, diabetes, and blood and immune system disorders when first attempted. "At issue is whether the 1.5 million fetuses aborted annually in the United States will be discarded or, with the woman's consent, be used for research and therapy that could benefit thousands suffering from Parkinson's disease and diabetes." [57]

The controversy involving fetal tissue research began after *Roe v. Wade* was decided in 1973. The prevalent source of the tissue for research was electively aborted fetuses. Opponents stressed that the procedure was "inextricably linked with the abortion debate… through fear that finding uses for [fetal] tissue would confer more respectability on abortion *per se* and… increase the pressure for abortions." [58] This situation could arise, proponents conceded, "if fetal transplants were so successful [with Parkinson's and diabetes patients] that demand outstripped supply or if the number of surgical family-planning abortions decreased."[59]

Noting this controversy, the Department of Health, Education and Welfare (HEW) created a commission in 1974 to promulgate regulations limiting the scope of research on the fetus. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed. The regulations it established stated that any experiments performed using dead fetuses must be done in accordance with state law. Under the Uniform

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[57] J. A. ROBERTSON, "Rights, Symbolism and Public Policy in Fetal Tissue Transplants", *The Hastings Center Report* 18/6 (1988), 5.

[58] A. R. BAUER, "Legal and Ethical Aspects of Fetal Tissue Transplantation", 1 (1994).

[59] J. A. ROBERTSON, "Rights, Symbolism and Public…", 7.

Anatomical Gift Act (UAGA) of 1968, state law treated fetal remains the same as other cadaveric remains and allowed next of kin to donate the tissue.[60]

Advocates of fetal tissue transplant invoked the framework of the UAGA to argue that fetal tissue donation paralleled adult organ donation. However, "there are enormous differences between fetal tissue transplants from induced abortions and adult organ transplantations from accidental deaths… render[ing] this parallel highly invalid."[61] One of these factors is that the death of the fetus is intentionally caused, not accidental. The analogy of transplants from homicide victims is not persuasive, as LeRoy Walters, the Commission's Chairman of Ethical and Legal Issues, pointed out. "If a particular hospital became the beneficiary of an organized homicide system which provided a fresh supply of cadavers, one would be justified in raising questions about the moral appropriateness of the hospital's continuing cooperation with the suppliers."[62] Another question is whether morally legitimate consent of next of kin is possible when it is the next of kin initiating termination of the pregnancy. Elimination of consent altogether, however, would further turn the unborn child into an object.[63]

After *Roe*, many states incorporated statutes regulating experimentation on aborted fetuses into their abortion codes.[64] One of these was Arizona. In 1984 it enacted statutes prohibiting experimentation on aborted human fetuses or embryos as a "class five felony" and as "unprofessional physician conduct."[65] The U.S. Court of Appeals for the Ninth Circuit ultimately struck down the statute in 2000 as constitutionally vague.[66] The concurring opinion of one of the judges illustrates how the ethos of society had changed from 1984 to 2000 with regard to abortion rights. He stated that Arizona must, "refrain from wielding its power and influence in a manner that might burden the pregnant woman's freedom to choose whether to have an

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[60] *Ibid*, 5.

[61] S. B. RAE, "The Ethics of Fetal Tissue Transplantation: Spare Parts from the Unborn", *Christian Research Institute Journal* DE192 (1992), 3.

[62] L. WALTERS, "Ethical Issues in Experimentation on the Human Fetus", *Journal of Religious Ethics* 2 (1974), 41, 48.

[63] Cf. S. B. RAE, "The Ethics of Fetal…", 4.

[64] 410 U. S. 113,162-65 (1973); see M. J. CLAPP, note, *State Prohibition of Fetal Experimentation and the Fundamental Right of Privacy*, 52 COLUM. L. REV. 1073 (1988).

[65] ARIZONA REVENUE STATUTE Sections 36-2302, 36-2303, 32-1401(25)(x) (1992).

[66] *Forbes v. Napolitano*, No. 99-17372, 2000 U.S. App., 12. Planned Parenthood of Central and Northern Arizona was a co-plaintiff in the case.

abortion," asserting that statutes prohibiting research on aborted fetal tissue could burden a woman's present and future reproductive decisions.[67]

Federal regulation of fetal experimentation was not addressed again until 1988, when the National Institute of Health (NIH) convened the Human Fetal Tissue Therapeutic Research Panel. The Panel's purpose was to evaluate a request for federal funding for the transplantation of fetal neural tissue into the brain of a Parkinson's patient. The request raised a new concern. The fetal cells and tissue in question would not be used just as a research tool, but as a source for transplantable tissue.[68]

A new awareness of the potentially lucrative fetal tissue market motivated the regulation of financial inducements governing the buying and selling of fetal tissue. This became an important element of the Panel's hearings. Hana Biologics, one of the firms testifying before the NIH Panel, estimated the total market for using fetal pancreatic tissue to treat diabetes to be approximately $6 billion annually.[69]

In an article published by the *Christian Research Institute Journal* in 1992, Scott B. Rae, Professor of Christian Ethics at Talbot School of Theology in Los Angeles, observes:

> "Abortion clinics stand to reap a substantial increase in revenue simply from the small amount (on average $25 per organ, multiplied by the hundreds of thousands of abortions performed annually) that the nonprofit acquisition organizations offer. The financial incentives to 'recruit' fetal tissue donors would be significant. Moreover, there are numerous noncash inducements that are difficult to detect and impossible to adequately police that would be especially appealing to poor and minority women. For example, the clinic could offer a 'discount' on the abortion procedure itself or promise to provide future medical care for a specified time following the donation of the tissue. With the anticipated profitability of the industry once the technology can alleviate a larger number of diseases, there will be increasing pressures to 'share the wealth' produced by these transplants."[70]

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[67] *Ibid*, 15. Concurring opinion by Judge Joseph T. Sneed.

[68] H. BOONSTRA, "Human Embryo and Fetal Research: Medical Support and Political Controversy", *The Guttmacher Report on Public Policy*, 4/1 (2001), 3.

[69] K. SOUTHWICK, "Fetal Tissue Market Draws Profit, Rebuke", *Health Week* 12 (1987), 1.

[70] S. B. RAE, "The Ethics of …", 4.

It was in this environment that the NIH Panel recommended certain parameters, subsequently adopted, seeking to insure ethically acceptable research. First, the decision to abort a fetus must be made prior to discussion of the use of fetal tissue. Second, anonymity was required to be maintained between the tissue donor and the tissue recipient. Third, timing and method of abortion could not be influenced by the possibility of tissue use. Fourth, consent of the pregnant mother was necessary and sufficient. Fifth, no financial or other incentives could be given to the woman aborting and donating the tissue.

In 1993, the National Institute of Health Revitalization Act (Act) was passed to codify the NIH Panel's above-referenced recommendations, along with existing regulatory provisions governing fetal tissue transplantation. The Act allowed aborted tissue to be used for transplantation research as long as the purpose of the research was "therapeutic." Therapeutic was defined as "clinical research performed on human subjects for the cure or amelioration of diseases or disorders."[71]

To ensure that this research did not encourage abortion, the Act included detailed informed consent safeguards, subject to outside audit. Informed consent was required by the woman donating the fetal tissue. The woman's physician was required to disclose any "interest" in research to be conducted on the tissue. Informed consent of the researcher was also required as to his awareness of the source of the tissue and his obligation to inform all other parties involved in the research. Significantly, the Act provided that the researcher must have "no part in any decisions as to the timing, method or procedure used to terminate the pregnancy made solely for the purposes of the research."[72]

A second provision of the Act set forth certain prohibited financial transactions relating to fetal tissue. It disallowed the purchase or sale of fetal tissue for a price above the reasonable payments needed to facilitate the research. It further disallowed the acquisition of fetal tissue through an agreement either to designate the recipient of the tissue or to implant the tissue into a relative of the donor. Finally, the Act prohibited providing "valuable consideration" for the

[71]42 U.S.C. Section 289g-1. The United States Code (U.S.C.) is a codification by subject matter of the general and permanent federal laws of the U.S.

[72]42 U.S.C. Section 289g, as amended by Section 498A.

expenses of the abortion. Valuable consideration was defined to "not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[73] Thus, fetal tissue could not be bought or sold either directly or indirectly. Only reasonable reimbursement of expenses was permitted.

Under the 1993 NIH Revitalization Act, the revised Uniform Anatomical Gift Act of 1987 (now applicable in all fifty states) and the National Organ Transplant Act of 1984,[74] human fetal tissue or organs cannot legally be bought and sold in the U.S. today. Money can change hands only to reimburse for actual expenses incurred.

In response to reports that these laws were being circumvented with respect to the sale of fetal body parts, the U.S. House of Representatives passed House Resolution 350 in November 1999 to investigate and conduct hearings on trafficking in fetal organs and tissue by private companies. In a letter to members of the House, which urged adoption of the HR 350, the United States Conference of Catholic Bishops (USCCB) wrote, "The urgency of such a resolution is obvious in light of recent disturbing reports, presenting credible evidence that private companies are working directly with the abortion industry in the trafficking and sale of fetal body parts, often harvested moments after an abortion to obtain 'fresh' tissue for researchers."[75]

3.2. Investigative Report

In March 2000, not long after House Resolution 350 was passed, the House of Representatives began hearings on the marketing of body parts obtained from fetuses killed in elective abortions. The information at the heart of the investigation was brought to light by Life Dynamics, Inc., a Texas non-profit pro-life organization founded by Mark Crutcher in 1992. The organization is known for its undercover investigations of abortion providers. This particular

[73] 42 U.S.C. Section 289g-2, as amended by Section 498B.

[74] The National Organ Transplant Act (1984 Public Law 98-507), approved in 1984 and amended in 1988 and 1990, outlawed the sale of human organs.

[75] G. QUINN, "Letter to Congress Concerning the Trafficking in Fetal Organs and Tissues by Private Companies", *U.S.C.C.B Pro-Life Activities* (1999), in http://www.usccb.org/prolife/issues/abortion/letnov8.shtml [8-2-2009].

investigation lasted approximately thirty-one months. Information was provided by employees of *Comprehensive Health for Women* (Clinic), a Kansas affiliate of Planned Parenthood.[76]

Life Dynamics' report describes a system devised within the abortion industry to financially profit from the growing market in fetal tissues, parts and organs. The system circumvents legal restrictions on buying and selling human bodies or body parts. Three participants are commonly involved---the "seller," the "buyer," and the "wholesaler." The wholesaler (or middleman) enters into a financial agreement with an abortion clinic (the seller) to pay a monthly "site-fee", comparable to rent, to the clinic. In exchange, the wholesaler is allowed to position a retrieval agent inside the clinic, where he is given access to the dead fetuses and a workspace to harvest their parts. In other cases, the retrieval agent may be a clinic employee who was trained by the wholesaler. The buyer is usually a researcher working for a medical school, pharmaceutical company, biotechnology company or government agency. When orders are received by the wholesaler from the buyer, they are faxed to the retrieval agent at the clinic who harvests the requested parts and ships them to the buyer via common carrier.[77]

> "On the surface, this system does not appear to violate the legal prohibitions against trafficking in human body parts since, technically speaking, no one is buying or selling anything. The loophole is that site fees and retrieval reimbursement amounts are unregulated. The law requires that such payments be reasonable and reflect the actual cost of securing the parts. But there are no state or federal laws which establish guidelines or set limits regarding these payments. Additionally, no government or law enforcement agency is charged with overseeing the system. This means that the wholesaler is free to set site fees at any amount."[78]

The fundamental legal question is whether site fees and retrieval reimbursements are used as proxy payments to circumvent state and federal laws making it illegal to buy or sell human body parts. For the transfers to be legal, the fetal parts and tissue must be donated, not sold. Only reasonable costs associated with the retrieval process may change hands.

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[76] M. CRUTCHER, *The Marketing of Aborted Babies*, Life Dynamics, Inc., Denton 2000.

[77] Cf. M. CRUTCHER, "Baby Body Parts for Sale!", *Life Dynamics.com* (2007),1, in http://www.lifedynamics.com/Abortion_Information/Baby_Body_Parts/index.cfm?&print=1 [3-1-2008].

[78] *Ibid*.

As outlined above, there are three entities in a position to profit from the fetal parts industry: (1) the abortion provider who supplies fetuses from abortions performed; (2) the wholesaler who fills researchers' orders by procuring the fetal parts, preserving them and preparing them for shipment, thus facilitating their transfer; and (3) the researcher who is the end user of the fetal parts. Technically, the abortion provider is permitted to receive only reasonable reimbursement for retrieval costs incurred. This amount is easily augmented through negotiation of favorable contract terms with the wholesaler, along with the application of some accounting ingenuity.

The wholesaler's profits can be substantial. There is generally a material difference between the amount it costs him to harvest fetal parts---consisting of his financial obligation to the abortion provider plus his administrative overhead expenses---over and above the amount he is able to realize from the researcher. The most significant profit potential, however, rests with the end-user, the researcher. These scientific researchers reside in educational and governmental institutions and the product-development departments of pharmaceutical, biotechnology and cosmetics companies. The prospects for profit here are virtually unlimited.

The Life Dynamics report illustrates the concepts discussed above with concrete numbers. During the undercover investigation, it was determined that the Clinic received monthly site-fees or rent supplements of $600 per month. In addition, they were paid $10 per hour for each hour the retrieval agent used a workspace at the abortion clinic. The Clinic received these payments without its having to incur any additional costs "just because the wholesaler's technician walked in the door." This makes it implausible that per-hour payments represented reimbursement for any actual costs associated with the retrieval of fetal parts.[79] During the period under review, the Clinic netted additional income of $1,200 per month from this arrangement.

Traveling up the fetal distribution chain, profits of the company acting as wholesaler were much higher. The wholesaler paid the Clinic an average of $1,200 per month. It also incurred costs for salaries of its retrieval agents, administrative overhead, amortization of

[79]M. CRUTCHER, "Baby Body Parts…", 4.

equipment (instruments, hood/dissection table, etc.) and disposable supplies. These costs were generously estimated to be approximately $5,500 per month. Total costs of $6,700 per month were paid, after inclusion of site-fee payments of $1,200 to the Clinic.

To compute the wholesaler's monthly net profit, gross revenue received from the researchers must be computed. Payment for specific fetal parts and tissues harvested was based on a price list called "Fee for Service Schedule" published by wholesaler Opening Lines, a Division of Consultative and Diagnostic Pathology, Inc. The fee schedule purports to estimate the reimbursable cost allocable to retrieving a particular body part, organ or tissue. If the laws against trafficking were being observed, the fees for providing the fetal parts ordered should essentially correspond to the wholesaler's costs of $6,700 computed above.

According to logs detailing tissue shipments, 155 specimens were shipped in a representative month. These specimens included 47 livers, 11 liver fragments, 7 brains, 21 eyes, 8 thymuses, 23 legs, 14 pancreases, 14 lungs, 6 arms, 1 kidney/adrenal gland and 3 intact specimens for purposes of securing the blood. When priced out according to the "Fee for Service Schedule,"[80] the shipment of parts for the month generated gross revenues of between $18,700 and $24,700, depending upon whether the parts were shipped fresh or frozen. Some sample prices for individual body parts from the above-referenced schedule are as follows: liver $150, pancreas $100, thymus $100, kidney $125, lungs and heart block $150, brain $999, spinal cord $325, bone morrow $350, eyes $75, gonads $550, intact cadaver $400, intact trunk with/without limbs $500, limbs (at least 2) $150.

These transactions resulted in a monthly profit to the wholesaler of between $12,000 and $18,000 (gross revenues of $18,700 to $24,700 less monthly costs of $6,700). The profits being earned by these middlemen are so significant, that it now appears that some researchers are cutting out the middlemen to deal directly with abortion clinics. In these cases, the site-fee and reimbursement system is replaced with a bartering-based system. One bartering example involved a medical school trading pathology reports for fetal cadavers and/or parts. "However, if

[80]According to the *Fee for Services Schedule* of Opening Lines, a Division of Consultative & Diagnostic Pathology, Inc. in West Frankfort, Illinois, these prices were in effect through December 31, 1999 for the listed fetal parts from fetuses over eight weeks gestation.

an abortion clinic is trading baby parts for services which it would otherwise have to pay for, and the school is trading services for baby parts it would normally have to buy, both are still in violation of those statutes which prohibit trafficking in human body parts."[81]

Ensuing chapters will explore in detail the financial gains available to the third participants in this economic arrangement---the researchers and the institutions and companies that become end-users of the intellectual property developed using fetal tissue.

Meanwhile, the results of the Congressional Hearings convened to investigate the practices uncovered by Life Dynamics are important to note. Nothing happened, leaving many frustrated by the lack of results produced. According to Mark Crutcher, lead investigative reporter, the hearings were doomed from the start by the national political system. The Democratic Party leadership is widely known to be beholden to the abortion industry for its significant financial support. What may be less widely known is that the Republican Party routinely receives substantial financial contributions from the pharmaceutical and biotechnology industries.[82] "These facts of political life made sure the hearings went no further. The biggest obstacle in trying to stop the trafficking of baby parts was the fact that the Democrats were in bed with the sellers and the Republicans were in bed with the buyers."[83]

In Chapter 1, "supply and demand" was defined as an economic model based on price, utility and quantity in a market. If the supply side is protected by one political party and the demand side by the opposition party, industries on both sides of the equation would appear to be in secure positions. With lucrative demand for fetal tissue having been created, both parties become part of a market force. This force must, by necessity, encourage expanding the supply of human fetal tissue to keep up with the demands of science, research and commerce.

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[81] M. CRUTCHER, "Baby Body Parts…", 8.

[82] OPEN SECRETS.ORG CENTER FOR RESPONSIVE POLITICS, "Pharmaceutical Manufacturing: Long-Term Contribution Trends", (2008), in http://www.opensecrets.org/industries/indus.php?ind=Q15 [5-25-2008].

[83] M. CRUTCHER, "Baby Body Parts…" 18.

3.3. Fetus Farming

A chapter on the fetal parts industry would be incomplete without a brief examination of fetus farming, described by Richard Doerflinger, Associate Director of the U.S. Conference of Catholic Bishops, as "a new slavery, with biotech companies as the plantation owners." Fetus farming is a method of obtaining whole organs or other complex tissues. Its purpose is to create and harvest body parts intended for trafficking.

Already progressing in animal models, researchers at Advanced Cell Technology, Inc. reported that cloned cow fetuses were created and gestated in-utero in adult cows. At four months, abortions were performed and liver tissue extracted from the cow fetuses was used in transplants.[84] Similar experiments have been done in mice and have provided usable tissues and organs.

According to Rev. Tadeusz Pacholczyk of the National Catholic Bioethics Center, "The prospect of fetal farming looms large… We have arrived at the point of creating human life merely to destroy it, harvesting it as little more than raw material, a commodity, for exploitation." Whole organs are exceeding complex structures. It is more practical for researchers to secure them from a fetus of eight months gestation, a stage appropriate for organ transplant, than a five-day old cloned embryo.[85]

A similar line of reasoning was advanced by Oxford University Professor Richard Gardner, advisor to Britain's Human Fertilization and Embryology Authority, in support of using organs from aborted fetuses for transplantation into adults. While such procedures have never been attempted in humans, research on mice has demonstrated that fetal kidneys develop quickly

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[84]R. LANZA - J. H. SHIEH - P. J. WETTSTEIN - R. W. SWEENEY - K. WU - A. WEISZ - N. BOTSON - B. HENDERSON - M.D. WEST - M. A. S. MOORE, "Long-Term Bovine Hematopoietic Engraftment with Clone-Derived Stem Cells", *Cloning and Stem Cells* 7/2 (2005), 95.

[85]Cf. T. PACHOLCZYK, "Fetal Farming and the New Slavery" *National Catholic Bioethics Center. Making Sense of Bioethics* in http://www.ncbcenter.org/FrTad_MSOOB_11.asp [9-1-2009].

inside adult animals. "Fetal-to-adult transplantation is "probably a more realistic technique in dealing with the shortage of kidney donors than others."[86]

Fetus farming could gain momentum if chemical abortions began to outpace surgical abortions, thus resulting in a reduction in the quantity and quality of fetuses available for research and development.

In 2004, New Jersey passed a law (S 1909) making it legal to create a cloned embryo, implant it in a woman's womb, then gestate it through the ninth month, so long as it is killed before birth. There is nothing in the law to prevent researchers from cultivating later-term cloned fetuses for spare parts; that is, fetus farming at taxpayer expense.[87] "Rather than restricting therapeutic cloning to the harvesting of stem cells from early embryos, as the industry often pretends in the media, the Biotechnology Industry Organization's (BIO) enthusiastic support of the New Jersey bill proves that [pro-cloning types] want an unlimited license to harvest cloned human life from inception through the ninth month."[88]

A member of President Bush's Council on Bioethics, Princeton University Professor Robert P. George, talked about how the New Jersey law could impact the financial landscape of the fetal parts industry. In his letter to New Jersey's Governor he says:

> "Although the legislation purports to ban trafficking in fetal body parts for 'valuable consideration', it expressly permits 'reasonable payment' for 'removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of embryonic or cadaveric fetal tissue'. This is a virtual invitation to cloning entrepreneurs to conduct in the State of New Jersey what would amount to fetal farming for research, presumably including experimental treatments. There seems to be nothing in the legislation to prevent cloning entrepreneurs from paying women a 'reasonable' fee to gestate embryos and submit to abortions for the production of human bodily tissues and organs. The entrepreneurs could then charge a 'reasonable' fee to their customers for

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[86] J. M. APPEL, "Are we Ready for a Market in Fetal Organs", *The Huffington Post* (17-3-2009), 1, in http://www.huffingtonpost.com/jacob-m-appel/are-we-ready-for-a-market_b_175990.html [1-9-2009].

[87] S. KLUSENDORF, "Betting the Farm", *Christian Research Journal* 29/4 (2006), 1.

[88] W. J. SMITH cited in K .J. LOPEZ, "State of Cloning: An Unprecedented Law in New Jersey", *National Review* (2004) in http://www.natioanlreview.com/lopez/lopez200401051346.asp [10-18-2009].

'processing,' 'preserving,' 'storing,' 'transplanting,' or 'implanting' fetal cadavers and tissues."[89]

Professor George predicted that if a legislative ban on fetus farming was not put into place, public opposition to the practice could erode. "People now find it revolting, but what will happen to public sentiment if the research is permitted to go forward and in fact generates treatments for some dreadful diseases or afflictions?" His fear was that moral opposition would collapse "when the realistic prospect of cures was placed before the public".[90]

Given these developments and the direction of the industry, the Fetus Farming Prohibition Act of 2006 was passed by Congress and signed into law by President Bush. The law expressly barred trafficking in embryos and fetuses with the intent of harvesting body parts. Many media outlets reported that the law was signed strictly for political purposes. Fetus farming, they maintained, was not actually being carried out, nor was it under serious consideration by the scientific community, calling the practice strictly hypothetical in nature. But other journalists went on record with different assertions, "Someday, if we are fortunate, scientific research may make possible farms of artificial wombs breeding fetuses for their organs."[91]

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[89] R. P. GEORGE, cited in K. J. LOPEZ, "State of Cloning: An Unprecedented Law in New Jersey", *National Review* (2004) in http://www.natioanlreview.com/lopez/lopez200401051346.asp [10-18-2009].

[90] R. P. GEORGE, "Fetal Attraction: What Stem Cell Scientists Really Want", *The Weekly Standard* 11/3 (2005), in http://www.weeklystandard.com/utilities/printer_.asp?idArticle=6119&R=1631528 [9-1-2009].

[91] J. M. APPEL, "Are we Ready…", 2.

Chapter 4

THE PHARMACEUTICAL INDUSTRY

It is critical for researchers conducting experiments with fetal material to develop procurement channels that can guarantee the delivery of an aborted fetus while it is still fresh. Dr. C. Ward Kischer, a leading authority on human embryology explains, "In order to sustain 95% of the cells, the live tissue would need to be preserved within five minutes of the abortion. Within an hour the cells would continue to deteriorate, rendering the specimens useless."[92] Who are the researchers that deal in human fetal tissue, how do they make use of the tissue obtained, and with which industries do they collaborate?

4.1. Industry Dynamics

The predominant industries engaged in fetal tissue research are part of the emerging life science industry: the pharmaceutical, biotechnology and biologics sectors. The pharmaceutical industry is involved in the discovery, development, production and marketing of drugs licensed as medications---whether they are prescription, generic or over-the-counter drugs. The field of biologics is narrower and typically involves highly specific and potent medicines derived from living cells, as opposed to chemical processes. It tends towards personalizing medicine through genetic testing and treating diseases at a molecular level. Biologics includes a wide range of medical products including bacterial and viral vaccines, blood and blood components, tissues, allergenics, somatic cells, gene therapies and recombinant therapeutic proteins created by biological processes.[93]

"Prior to the creation of biotechnology," reports the Biotechnology Industry Organization (BIO), "pharmaceutical companies produced drugs and vaccines without the genetic information that is available today. Biotechnology revolutionized drug design and development by using specific scientific knowledge about living organisms, including genetic and molecular

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[92] D. L. VINNEDGE, "Aborted Fetal Cell Line Vaccines and the Catholic Family", *Children of God for Life*, in http://www.cogforlife.org/fetalvaccinetruth.htm [6-7-2009], 4.

[93] U. S. FOOD AND DRUG ADMINISTRATION, "Vaccines, Blood and Biologics", *Resources for You (Biologics)*, in http://www.fda.gov/BiologicsBloodVaccines/resourcesfor you/default.htm [9-9-2009].

information, for the advancement of research and applications in the pharmaceutical industry."[94] This biopharmaceutical product market was worth more than $35 billion in 2002 and is growing… In fifteen to twenty years, it is expected to reach $200 billion.[95]

Since the early 1980's, the pharmaceutical industry has consistently ranked as the most profitable industry in the United States among all industries listed in the Fortune 500.[96] Estimated U.S. sales for prescription drugs amounted to $291.5 billion in 2008, having grown consistently over the past three decades.[97] The extraordinary thing about pharmaceutical companies is not only the amount of gross revenue they generate, but also the percentage of profit earned on that revenue (net profit divided by gross revenue equals profit percentage). The industry's largest companies averaged a 16% profit rate on sales revenues in 2008, compared with a median profit rate of 3% for the other Fortune 500 companies. Some of the top drug companies earned an even higher profit percentage, with industry giant Pfizer at 17%, Amgen at 21% and Glaxo/Smith/Kline at 23%. During the past decade, Eli Lilly has been as high as 24%, Pfizer 26%, Wyeth an astounding 30%.[98]

Two developments took place in 1980 leading to this explosive growth and profitability and presenting tremendous potential advantages to both big pharma and small biotech. "Congress enacted a series of laws designed to speed the translation of tax-supported basic research into useful products."[99] The most significant and far-reaching of these laws was the Bayh-Dole Act. The same year, a Supreme Court decision dramatically changed the patent law landscape as to the patenting of living organisms "The Bayh-Dole Act enabled universities

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[94]The Biotechnology Industry Organization (BIO) is the world's largest biotechnology organization, providing advocacy, business development and communications for over 1,100 members in the U.S. This information is taken from its 2005 publication, *BayBio IMPACT*.

[95]"Biotech Alliance of DSM Biologics & Crucell--For Faster Preparation of New Medicines at Lower Cost", Crucell press release, December 19, 2002, in http://cws.huginonline.com/C/132631/PR/200212/886064_5.html [8-31-2006].

[96]The Fortune 500 is an annual list compiled and published by Fortune Magazine that ranks the top 500 U.S. closely-held and publicly-held corporations, ranked by their gross revenue.

[97]IMS HEALTH, "Total U.S. Prescription Market Revenues", in http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StatisticsFile/Top_Line_Data/2008 [9-9-2009].

[98]MONEY MAGAZINE, "Fortune 500", in http://www.money.cnn.com/magazines/fortune/fortune500/Industires/21/Index.html [9-4-2009].

[99]M. ANGELL, M.D., *The Truth About the Drug Companies*, Random House, New York 2004, 7.

and small businesses to patent discoveries emanating from research sponsored by the National Institute of Health (NIH), the major distributor of tax dollars for medical research. The Act further allowed them to grant exclusive licenses to drug companies. Until then, taxpayer-financed discoveries were in the public domain, available to any company that wanted to use them. But now, universities, where most NIH-sponsored work is carried out, could patent and license their discoveries and charge royalties."[100]

On June 16, 1980, in a reversal of decades of prior law, the Supreme Court ruled against the U.S. Patent Office in *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty.*[101] Author Melody Peterson describes how this decision ushered in the commodification of human body parts in the United States:

> "The Supreme Court unleashed a deluge of industrial science by allowing the first patent to be placed on a living organism, a bacterium genetically engineered by a scientist at General Electric to devour oil spilled into the sea. Patents are vital to industry. They give inventors monopolies on products by preventing competitors from selling them for twenty years. The Supreme Court ruling reversed that of the U.S. Patent Office, which had long held that living things could not be patented. The decision opened the door to the patenting of genes, cell lines, tissues and organs. Human parts became products. Medicine became a golden business opportunity. These two changes---the Bayh-Dole Act and the ability to patent biological things---put dollar signs into the eyes of college administrators and their faculties. Universities began to see their medical laboratories as profit centers and their professors as entrepreneurs."[102]

One of the practical results of these developments was to transform non-profit medical schools and teaching hospitals into entrepreneurial institutions with a financial stake in the studies they were carrying out, creating a pro-industry bias in medical research.

The critical strategy became a rush to market with new drugs. With patent laws structured to extend monopolies on products, it was financial failure for a company not to get a blockbuster drug to market first. Large pharmaceuticals bought innovative biotech start-ups, often founded by academics who held useful patents on NIH-funded research. This was an

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[100]M. ANGELL, M.D., *The Truth About…,* 7.

[101]*Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 447 U.S. 303,206 USPQ 193 (1980).

[102]M. PETERSON, *Our Daily Meds,* Sarah Crichton Books, New York 2008, 178-179.

economical alternative to engaging in their own expensive private research and development. Ironically, the drug industry argued that its extraordinary profit margins, built on high prices, were required to fund expensive and risky research and development. But in reality, drug companies were not the ones actually doing the research. The biotech start-ups being acquired were the companies producing and holding rights to the innovative technologies.

Whether fetal tissue research offered anything to learn that could not also be learned by using adult tissue is arguable. Its overriding advantage was its ability to grow and develop more rapidly. For a company attempting to win the race to market, time was of the essence. The demand for fetal tissue created by the life science industry was growing at a rapid pace, particularly for the purpose of replacing and improving on existing fetal cell lines for research and for use in the pharmaceutical industry.[103]

This state of affairs leads back to ongoing policy and ethics issues being debated across the political landscape. The drug companies through their lobbying arm, the Pharmaceutical Research and Manufacturers of America (PhRMA), had become one of the most powerful political forces in the country. Dr. Marcia Angell states, "As their profits skyrocketed during the 1980's and 1990's, so did the political clout of drug companies. By 1990, the industry had assumed its present contours as a business with unprecedented control over its own fortunes. For example, if it didn't like something about the Federal Drug Administration (FDA), the federal agency tasked with regulating the industry, it could change it through direct pressure or through its friends in Congress."[104] In 2002, the industry spent a record $91.4 million on lobbying activities. An additional $50 million was spent on advertising, public relations, direct mail, telemarketing efforts, and grants to advocacy groups and academics advocating the industry's positions.[105] Given the magnitude of pharmaceutical profits at stake, it would seem that lobbying had become a prudent and relatively inexpensive insurance policy.

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[103]Cf. A. WONG, M.D., "The Ethics of HEK 293", *The National Catholic Bioethics Quarterly* 6/3 (2006), 491.

[104]M. ANGELL, M.D., *The Truth About…,* 10.

[105]C. AARON - T. LINCOLN, *The Other Drug War 2003: Drug Companies Deploy an Army of 675 Lobbyists to Protect Profits*, Public Citizens Congressional Watch, Washington DC 2003, 1.

The pharmaceutical industry recognized its potential to amass considerable gains from the legal and expanding fetal tissue industry. It had the money and influence to do so. Vaccine development was an ideal vehicle to realize this potential.

4.2. Vaccines

Historically, the commercial use of fetal tissue has revolved around the production of vaccines. Several commonly-used vaccines are cultured on human diploid fibroblast cell strains derived from electively-aborted human fetuses. HDCS refers to groups of human diploid cell strains that maintain normal human chromosomal numbers and characteristics, while dividing throughout their limited lifetime in a laboratory setting. Cells taken from fetuses aborted in the 1960's, 1970's and 1980's were used to develop HDCS, which were then used to manufacture a number of childhood and adult viral vaccines. To make viral vaccines, viruses are grown in HDCS or animal cells and incubated until enough virus is available for harvest.[106]

"The choice of HDCS was made among several based on their susceptibility to many viruses, their good characterization, the enormous number of cells obtained from one culture, their long storage potential, the low cost of cell procurement, an excellent record of safety, and the very low risk of latent virus on the cells themselves."[107] This speed and stability enhanced their economic soundness.

The original fetal cell strain used in viral vaccine manufacture, WI-38 (Wistar Institute cell strain 38), was developed in the 1960's. It was put to commercial use during the rubella outbreak of 1964. Three institutes came together to collaborate on this ground-breaking research: (1) the Karolinska Institute of Stockholm, Sweden, which supplied the fetuses (abortion was illegal at this time in the U.S.); (2) the Wistar Institute of Anatomy and Biology at the University of Pennsylvania, where the research was carried out by Leonard Hayflick; and (3) the

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[106] LIFE CANADA, INC., "Viral Vaccines & Aborted Fetal Tissue: Common Questions & Answers", in http://www.lifecanada.org/html/science/Aaccines/VaccineQuesionandAnswers.html [9-3-2009].

[107] M. A. FLETCHER - L. HESSEL - S. A. PLOTKIN, "Human Diploid Cell Strains (HDCS) Viral Vaccines", *Developments in Biological Standardization* 93 (1998), 97-107; L. HAYFLICK, "History of Cell Substrates Used for Human Biologicals", *Developments in Biological Standardization* 70 (1989), 11-26.

Merck Research Institute, "who assisted in the research and, as the sole manufacturer of the only rubella vaccine available in the U.S., had a vested interest in the results."[108]

The cell strains developed were derived from tissue taken from the lungs, skin, kidneys, muscles, heart, thymus, thyroid and liver of twenty-one separate electively-aborted fetuses. According to Dr. Hayflick, "One fetus can be the source of a cell strain with a potential yield of about 20 million metric tons (wet weight) of cells, which can be stored frozen for many years. Many vaccine lots can be produced in cells from a single tested HDCS over a length of time. In addition, aborted fetuses and/or their organs are seemingly easy to obtain, and the cost of tissue procurement is negligible."[109]

In 1981, Leonard Hayflick acquired the patent for WI-38, which had been developed in 1963. In 2007, he stated, "WI-38 was and still is used as the substrate to produce most human virus vaccines which have been administered to more than a billion people around the world during the last forty years."[110]

Besides WI-38, there are other human diploid cell strains in use. MRC-5 (Medical Research Council cell strain 5), utilized at least as extensively as WI-38, was developed in 1966 from lung tissue taken from a fourteen-week old fetus aborted for psychiatric reasons of the mother. IMR-90 (Institute for Medical Research cell strain 90) was derived from the lungs of a sixteen-week old female fetus aborted in 1975. It is designated for research and related activities. The human embryonic kidney (HEK) 293 cell line was developed in 1973 from fetal kidney and is widely used in laboratory research. Its most common use is in gene therapy to propagate adenovirus, a vehicle for delivering experimental genes.[111] The virus strain RA 27/3 was obtained in 1964 from a female fetus whose mother had been exposed to rubella. The rubella virus strain was grown on WI-38.

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[108] D. L. VINNEDGE, "Aborted Fetal Cell…", 5.

[109] L. HAYFLICK, "The Choice of the Cell Substrate for Human Virus Vaccine Production", *Laboratory Practice* 19 (1970), 60.

[110] L. HAYFLICK, "Letters: The Never Ending Story of HeLa", *Scientist* 20 (2007), 14.

[111] A. WONG, M.D., "The Ethics of HEK…", 474-476.

The PER.C6 cell line was developed in 1995 from embryonic retinal cultures obtained from a 1985 elective abortion. The medical details regarding this abortion were documented thoroughly because, from the beginning, the intent was to develop this line as a basis for vaccine and pharmaceutical manufacturing. The researchers knew the line would be submitted for Federal Drug Administration (FDA) licensure and scrupulous documentation would be needed.[112] PER.C6 will be examined more fully in the case study to follow. The case chronicles the business activities of Crucell N.V., a Dutch biopharmaceutical development company.

Table 3 below summarizes the aborted fetal cell line products widely marketed in the U.S. and Canada by disease inoculated against and drug-company manufacturer.[113] The list is representative but not comprehensive.

Table 3

Disease	**Manufacturer**	**Fetal Cell Line**
Chickenpox	Merck, Glaxo/Smith/Kline	WI-38, MRC-5
Hepatitis A & B	Merck, Glaxo/Smith/Kline	MRC-5
Measles/Mumps/Rubella	Merck, Glaxo/Smith/Kline	RA 27/3, WI-38, MRC-5
Polio	Sanofi Pasteur (Aventis)	MRC-5
Rabies	Sanofi Pasteur (Aventis)	MRC-5
Rheumatoid Arthritis	Amgen	WI-26, VA-4
Sepsis	Eli Lilly	HEK-293
Shingles	Merck	WI-38, MRC-5
Smallpox	Acambis	MRC-5
Flu, Avian Flu, Sine Flu*	Crucell, Sanofi Pasteur	PER.C6
HIV*	Merck	PER.C6

*In Development

[112]T. P. COLLINS, M.D., "Human Technology Manufacturing Platforms", *The National Catholic Bioethics Quarterly* 6/3 (2006), 505.

[113]CHILDREN OF GOD FOR LIFE, "U.S. and Canada-Aborted Fetal Cell Line Products and Ethical Alternatives", (2009), in http://www.cogforlife.org [9-4-2009].

Varicella (chickenpox) is the only disease for which there is no vaccine free of any connection with abortion. An untainted vaccine against rubella (German measles) exists in Japan but does not have FDA approval and thus, has not been marketed in the U.S.

4.3. Human Technology Manufacturing Platforms

Until now, the discussion has been limited to vaccine production---mainly pediatric vaccines. The population affected with the choice of underwriting the fetal-cell-developed vaccine market has generally been confined to parents of vaccination-age children. This is changing. The PER.C6 fetal cell line is leading the drug industry into ever more diverse biopharmaceuticals through its introduction as a versatile manufacturing platform, which is adaptable to other applications. As noted in Table 3, this line is currently under development for use against various flu strains and most significantly, HIV.

Crucell is the company that developed and licensed PER.C6 (its registered trademark). Originally formed with the intent of using stem-cell technology to advance gene therapies, Crucell's predecessor company recognized that existing technologies were developed primarily for research. They would not meet pharmaceutical industry standards. This prompted collaboration with Leiden University, the oldest university in the Netherlands, to develop PER.C6. By 2001, the cell line was being reported on in scientific literature as a "new manufacturing system for the production of influenza vaccines."[114] By 2002, the line was further expanded on a commercial scale as a "broadly applicable human technology platform" for developing pharmaceuticals, specifically Merck's HIV vaccine research program.[115] According to Crucell's website, PER.C6 would be used as a manufacturing system "on which a wide range of biopharmaceuticals can be developed, such as vaccines, antibodies, therapeutic proteins and gene therapy products." Crucell boasted a market capitalization of 735 million Euros in 2005.[116] It eventually licensed PER.C6 to over fifty companies, including Merck.

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[114]M. G. PAU et al., "The Human Cell Line PER.C6 Provides a New Manufacturing System for the Production of Influenza Vaccines", *Vaccine* 19.17-19 (2001), 2716-2721.

[115]"Crucell's PER.C6 Cell-Line Used in Merck's HIV-1 Vaccine Research Program", *United Business Media PR Newswire*, (2001) in http://www.prnewswire.com [4-3-2001].

[116]Cf. T. P. COLLINS, M.D., "Human Technology Manufacturing…", 506.

Effective pharmaceutical lobbying has resulted in many government contracts being awarded for PER.C6-related research. Among these are funding arrangements with the U.S. Department of Health and Human Services (HHS) through its branches, the National Institute of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID).

In 2004, Vaxin, an Alabama biotechnology company, announced a licensing agreement with Crucell to use the PER.C6 fetal cell line to develop vaccines against a number of diseases including anthrax and respiratory syncytial virus, as well as in an innovative inhaled vaccine against influenza.[117] Vaxin has been awarded over $10 million in federal funds for research and development on the PER.C6 line. In 2005, the Sanofi Aventis Group announced it had been awarded a $97 million contract by HHS. The contract's purpose was to speed the production process for new cell-culture influenza vaccines in the U.S. by developing the PER.C6 vaccine and designing a new PER.C6 cell-culture manufacturing facility in Swiftwater, Pennsylvania.[118] Later that year, HHS awarded Sanofi an additional $150 million to manufacture vaccine in bulk from the Swiftwater location.

Many other institutions are licensing Crucell's PER.C6 cell line or entering into joint ventures with Crucell. Walter Reed Army Institute of Research is evaluating it for the development of vaccines against Japanese encephalitis, dengue fever and West Nile fever viruses. The Aeras Global TV Vaccine Foundation, whose major funders include the U.S. Center for Disease Control and Prevention (CDC) and the Bill and Melinda Gates Foundation, contracted with Crucell for $2.9 million to develop a new tuberculosis vaccine using PER.C6. Merck licensed PER.C6 in 2001 in connection with the development of its HIV-1 vaccine, which moved into phase I clinical trials in 2002 and is poised to move into the next phase in the near future.[119]

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[117]"Crucell and Vaxin Announce PER.C6 Licensing Agreement", Vaxin Press Release September 13, 2004, in http//www.vaxin.com/CrucellAnnounce.pdf.

[118]"Sanofi Pasteur Awarded $97 Million in HHS Contract to Accelerate Cell-Culture Pandemic Influenza Vaccine Development", Sanofi Aventis Press Release, April 1, 2005, in http://www.en.sanofi-aventis.com/Images/050405_cell_culture_final_en_tem24-2330.pdf.

[119]Cf. T. P. COLLINS, M.D., "Human Technology Manufacturing…", 509-511.

In 2002, the PER.C6 line was launched into commercial production of fully human monoclonal antibodies (MAb), according to Crucell's corporate history. MAb therapies are unconnected to vaccine production and are "increasingly used in cancer therapies, as they are directed at specific antigens found on the malignant cells." Crucell and many other biotech companies are aggressively pursuing MAb development using human lines like PER.C6.[120]

There appears to be vast profit potential for the biopharmaceutical industry in the development of human technology manufacturing platforms. The industry has at its disposal the means to exploit this market exponentially. The foregoing history of the development of a single fetal cell line, PER.C6, indicates the potential that exists. But how long will it take for drug companies to stop paying to license another's cell-line technology in favor of developing their own? Cell lines are not immortal,[121] as was once believed, and more will be needed to keep pace with scientific and technological discoveries. The door is open to development of additional human diploid cell strains, which will require more fetal tissue.

Are there viable alternatives to using human technology manufacturing platforms? Many scientists have affirmed that there are. Vaccines and monoclonal therapies can be developed without them. For example, "the use of recombinant DNA technology could lead to the development of new vaccines in the near future which will no longer require the use of cultures of human diploid cells for the attenuation of the virus and its growth. Such vaccines will not be prepared from a basis of attenuated virus, but from the genome of the virus and from the antigens thus developed." [122] This presents a scientifically valid and ethical alternative to the use of aborted fetal tissue cells.

Will these more ethical alternatives be pursued? "Admittedly, once a scientific or industrial procedure is set in place, it is difficult and perhaps costly to develop an alternative

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[120] T. P. COLLINS, M.D., "Human Technology Manufacturing…", 511.

[121] One of the key arguments originally advanced by ethicists was that there would be no need for further fetal tissue since the existing cell lines are "immortal." Ultimately, these theories were proven false when it was demonstrated that all normal cell strains, animal or human, have a finite lifespan which is directly proportionate to the age of the cell donor.

[122] G. C. WOODROW, "An Overview of Biotechnology as Applied to Vaccine Development", *New Generation Vaccines*, Marcel Dekker, New York, 1990, 32-37; S. K. ASKARIM, "Immunization", *JAMA*278/22 (1997), 2005-2006.

method. Yet, however impractical it may be, one should not say that it is impossible."[123] However, "the reality is that pharmaceutical manufacturers and biotechnology companies are moving forward at a fast pace on the development and implementation of human technology manufacturing platforms, aided and abetted by taxpayers' dollars, because such technologies are laden with profit, both current and prospective. The manufacturers know what they are doing and they are not going to stop."[124] If the past can be used as a barometer of the future, it seems unlikely that industry will voluntarily turn away from a more straightforward path to profits.

[123] A. WONG, M.D., "The Ethics of HEK…", 491.
[124] T. P. COLLINS, M.D., "Human Technology Manufacturing…", 514.

Chapter 5

THE COSMETICS INDUSTRY

Although there is much money to be made in the pharmaceutical industry, many working therein are undoubtedly motivated by the altruistic belief that they are working in service of humanity. It is possible to rationalize moral reservations about the source of fetal material from the conviction that they are acting to reduce human suffering. But what if the end does not justify the means? What if the end is so superficial that, instead of serving humanity, it is vanity that is being served?

In his article, "Fetuses Harvested for Cosmetic Procedures," Dr. Michael Arnold Glueck brings the problem into focus in his first paragraph.

> "Lawyers love to talk about the slippery slope, how you bend the rules a little or do something a little wrong and it leads inevitably to worse. But sometimes the slope turns into a precipice and you find yourself looking into the abyss. Use of fetal tissue for cosmetic purposes, especially fetal tissue conceived only for that purpose, is such a precipitous plunge. The scientific and medical community knew it would happen eventually but didn't know how soon. False hope for stem cells is cruel enough, but using stem cells from fetuses created for monetary gain to use for cosmetic purposes seems to cross the moral line."[125]

5.1. Cosmeceutical Development

Anti-aging cosmetics developed using fetal stem cells fall into the loose and unofficial category of "cosmeceuticals". This term, coined simply for marketing purposes, refers to a marriage between cosmetics and pharmaceuticals. Like cosmetics, cosmeceuticals are topically applied but contain active ingredients purported to have medical or drug-like benefits that influence the biological function of the skin. Some biotech companies have turned to the development of these beauty products. They hope the products will generate an early return on

[125] M. A. GLUECK, M.D. - R. J. CIHAK, M.D., "Fetuses Harvested for Cosmetic Procedures", *The Medicine Men* (2006), in http://www.archive.newsmax.com/archives/articles/2006/8/23/155813.shtml [6-29-2009].

the lavish investments being made in stem-cell technology, knowing that prospects for therapeutic applications remain vague and distant.

The U.S. Food and Drug Administration (FDA) does not recognize the category of cosmeceuticals under its Federal Food, Drug and Cosmetic Act, nor are these compounds subject to review and approval by the agency. Although they are tested for safety, testing to determine whether beneficial ingredients live up to manufacturers' claims is not mandatory.[126] It is actually beneficial to a manufacturer if its products are not regulated as drugs by the FDA. The review process is costly and may prevent or delay introduction of a marketable product.

The genesis of using fetal tissue for cosmetic purposes arose out of its successful clinical use in burn victims. Stem-cell based cosmetic lines expanded on treatments employing fetal skin cell cultures to heal second and third-degree burn wounds in children. After years of research, physicians discovered that fetal skin has a unique ability to heal wounds without scarring. "The research team, based at the University Hospital of Lausanne, Switzerland, obtained a four-centimeter skin donation from a fourteen-week aborted male fetus. Cells were expanded in culture and used to seed collagen sheets, and then grown for two more days until the sheets were applied to burn wounds. The fetal cells were used to treat eight children considered to be candidates for traditional grafting…The cosmetic and functional results were excellent in all eight children."[127]

From the above-referenced fetal skin biopsy, the University Hospital of Lausanne research team went on to establish a dedicated cell bank for developing a cream designed to reduce signs of aging and improve skin texture and the appearance of wrinkles. It is alleged that this fetal cell bank will provide a lasting supply of cells for producing a proprietary skin-care ingredient. The active ingredient, trademarked by Neocutis S.A. as Processed Skin Care Proteins or PSP, is a combination of human growth factors and cytokines (intercellular messengers).

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[126]Federal Food, Drug and Cosmetic Act, enacted in 1938, including amendments through 2005, Chapter VI, Sections 601-603; U.S. Code Sections 361-363.

[127]K. GALE, "Fetal Skin Cells Help Heal Burn Wounds in Children", *The Lancet* (18 August 2005) http://www.redorbit.com/news/health/212483/fetal_skin_cells_help_heal_burn_wounds_in_children.html [6-2-2009].

Neocutis S.A., a privately-held specialty bio-pharmaceutical company, was founded in 2003 as a spin-off of the University Hospital of Lausanne. Commercial activities are carried out by its U.S. subsidiary, Neocutis, Inc.[128] Creation of the company replicates the pattern developed by the pharmaceutical industry, where hospital research personnel become founding entrepreneurs of commercial enterprises based on their successful research.

5.2. Market Demographics

The cosmetic industry in general and the anti-aging market in particular have benefited from three factors converging to provide a perfect storm for business development. These three factors---a record number of consumers, a high level of affluence and a fear of aging---came about as a result of the so-called "baby boom" following World War II. Between the years 1946 and 1964, 75 million babies were born in the United States, according to the U.S. Census Bureau. Today, this age group earns over two trillion dollars, controls seven trillion dollars of wealth, and owns over 77% of financial assets in the U.S. They account for 28% of the U.S. population.[129]

This is a generation that believes it can stay young forever and is equipped with the resources to try. They are a captive market. One company's marketing strategy speaks of the opportunity to cash in on this phenomenon. "The boomers are commanding attention with their voices and their wallets as they will be the primary contributors to the projected $12 billion increase in money spent on anti-aging products and supplements in the next year and a half alone…The anti-aging market is presently a $30 billion market. In the next three years, it is expected to grow to $70 billion… This is the fastest growing market in the U.S."[130]

"The promise of stem cells in dermatological reconstructive surgery," says author Bryn Nelson of Nature Publishing Group, "has prompted a surge in rejuvenating skin creams that

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[128] Information available on Neocutis S.A. website, in http://www.neocutis.com [10-12-2009].
[129] United States Census Bureau, in http://www.census.gov/popest/national [10-12-2009].
[130] WAIORA INDEPENDENT DISTRIBUTORS, "Zeolite Marketing and the Anti-Aging Market", in http://www.zeolitemarketing.com/anti_aging_market_.html [10-12-2009].

claim to stimulate them."[131] The fetal-cell anti-aging market is limited only by the amount of money available to be spent for products and procedures promising youth, beauty and vitality.

At the "low" end, miracle claims are made for creams, serums and emulsions developed with fibroblasts and human growth factors; i.e.; fetal cell technologies. Most are produced in the U.S. and none of their claims have been evaluated by the FDA. All are unproven as to efficacy. One product, Amatokin, produced by Voss Laboratories, costs $190 for 30 milliliters or one ounce. A direct competitor, ReVive Skincare's Peau Magnifique, retails for $1,500 for four one-milliliter ampoules. Another anti-aging treatment by Neocutis marketed as Journee Bio-Restorative Day Cream with PSP, can only be purchased through offices of a doctor or dermatologist and its price is kept confidential from the general public.[132] The products are expensive because they are not mass produced and have a very limited shelf life.

At the "high" end, exclusive clinics in various worldwide tourist locations are offering face lifts and cosmetic procedures using tissues from aborted fetuses and stem cells from human embryos. The cells are said to rejuvenate the skin.[133] Wealthy American and British women, who cannot avail themselves of these treatments at home due to regulatory restraints, travel to a particular tourist destination in Barbados. Here they spend $25,000 per session on a "treatment consisting of having liquefied fetal tissues injected into their bodies so they can feel refreshed." The CEO of the Institute for Regenerative Medicine in Barbados, where this transpires, promises improvement in appearance, quality of life and libido. These clinics are not regulated by any local or national government body, nor do they have any form of outside medical supervision. They have all refused membership in the International Stem Cell Forum, the only recognized international board regulating ethical stem-cell research.[134]

Until recently, the raw materials for producing these liquefied fetal serums for injection were imported to Barbados from the Ukraine. "Women were paid $200-$300 (three months

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[131]B. NELSON, "A Superficial Success", *Nature Reports: Stem Cells* 10.1038 (2009), in http://www.nature.com/stemcells/2009/0901/090115/full/stemcells.2008.163.html [5-7-2009].

[132]Cf. *Ibid*.

[133] M. A. GLUECK, M.D. - R. J. CIHAK, M.D., "Fetuses Harvested for…".

[134]B. CLOWES, "Special Report: Ukrainian Trafficking in Baby Parts", *Human Life International* 270 (2007), 2.

salary) to carry their pregnancies to a very late stage and then deliver the babies alive in a kind of forced premature birth. The procedure allows the living baby's organs to be harvested while they are still as fresh as possible."[135] The parts are passed on to buyers, who screen the material and sell it at a huge mark-up to a worldwide network of clinics like the one in Barbados. In Moscow alone, there are more than fifty beauty parlors and cellulite clinics offering fetal injections. These establishments attract rich Russian and Western women for fetal injections to "eliminate cellulite from their buttocks, thighs and arms." Treatments cost up to $20,000.[136] The fetal and newborn tissue machinery is driven by an enormous and increasing demand for fetal cells and organs for this purpose.

Brian Clowes, the investigative reporter who uncovered this story for Human Life International, questions why the Institute for Regenerative Medicine in Barbados would "bother to import babies from 5,000 miles away [in the Ukraine] when you can get them locally?" He answers his own question below.

> "Barbados news sources are now reporting that women are having their newborn babies stolen at Queen Elizabeth Hospital. They are told their babies are 'gone' or have died, and they never see them again. Perhaps not coincidentally, one of the members of the Board of Directors of Queen Elizabeth Hospital is George Griffith, who is the director of the Barbados Family Planning Association, the island's largest abortion provider and an affiliate of the International Planned Parenthood Federation."[137]

Even the most ardent advocates of fetal tissue research express dismay at these cosmetic procedures fraught with abuses. It is an understatement to say this use of science and technology is not only dangerously experimental, but also damaging to the reputation of legitimate researchers. New and profoundly disturbing motives leading to expanded trafficking in human body parts are being introduced.

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[135] B. CLOWES, "Special Report: Ukrainian…", 4.
[136] Cf. *Ibid.*
[137] *Ibid.*, 6.

Chapter 6

ETHICAL ASSESSMENT

6.1. The Human Person

If the transcendence of man is not recognized and respected, if he is not accepted as a creature endowed with absolute value, he is easily reduced to a commodity. "Mechanism reduces the living being to an aggregate of substances acting one upon another in a complex physico-chemical activity. This theory is called 'mechanism' because it reduces physico-chemical activity to mechanical action (local motion), denying the specific difference between what is living and what is non-living. A living being would be no more than a more perfect machine, reducible to and divisible into its elements."[138] This is the premise on which vaccine production and cosmetic-injection development from human fetuses is based. The human body is a mass of chemicals. As such, it is viewed through the lens of profit. If human beings are not exceptional in the material creation, the vision of man as a profit center may well be acceptable. In some stages of life, he is the supplier; in some stages, the consumer. But always, profit is the motive.

In a capitalistic society, things are evaluated according to their usefulness or utility. Jeremy Bentham, advocate philosopher of utilitarianism, defined utility as "that property in any object whereby it tends to produce benefit, advantage, pleasure, good or happiness." [139] Utilitarianism maintains that an action is valuable essentially as a means, making consequences the test of right or wrong, without reference to man's finality. Contrary to the Pauline principle, "You shall do no evil that good may come of it,"[140] people routinely rationalize, accept and cooperate with evil in its many disguises, often denying its very existence, so long as the profits are high enough.

In observing the various stages of life, mankind is commonly regarded as most vulnerable at its very beginning and very end. On a physical level that is quite true. The embryo and fetus,

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[138] R. LUCAS LUCAS, *Man Incarnate Spirit…, 29.*
[139] J. BENTHAM, *Introduction to the Principles of Morals and Legislation*, Oxford, 1823.
[140] *Romans 3:8.*

the old and infirm, are more susceptible to abuse than those engaged in the more active stages of life. In the context of utilitarianism each of these stages represents a non-productive, non-income producing financial burden to the system. Yet psychological exploitation also makes men and women vulnerable at any age. Expensive and skillful advertising and marketing campaigns have proven successful in engineering cultural preferences, sometimes at the cost of jettisoning any and all ethical restraints. Wants and needs are created in the general population by appealing to fear of human frailty in order to sell perpetual youth and health. Without an orientation towards truth and justice, those who exploit the market and those who bow to popular culture have no ethical foundation.

6.2. The Past and the Future

This is not the first time the human person has been at the center of a commercial enterprise. Seeking parallels in history recalls the profitable slave trade. Introduced into the United States in the 1630's, slavery had become entrenched in the southern states by 1860, where slaves' productivity brought prosperity to plantation owners. Its abolition was possible only by means of a civil war that nearly destroyed America. Two hundred thirty years of slavery had long illuminated its poisonous effects as a social institution, but profit proved an intractable and powerful adversary. The slave trade was a strong commercial enterprise and benefited from government protection. The rules, laws and social norms that were adopted during this historical era made slavery possible. The distinct legal status given to slaves under the law, that of property or chattel, turned human beings into commodities to be bought and sold, traded and exploited. The purchase of slaves was a profitable investment yielding a high rate of return. Thus, slavery became an essential factor in the growth of agriculture, predominantly in the cotton, sugar and tobacco industries.[141]

Even in the present day, many African-Americans continue to experience the aftermath of slavery as a subtle attitude exhibited by prejudice and discrimination. The knowledge that eugenic reasons for abortion still exist and claim three of five black babies has prompted cries of

[141] R. FOGEL - S. ENGERMAN, *Time on the Cross: The Economics of American Negro Slavery*, Little, Brown & Company, Boston 1974.

"black genocide" from Dr. Rev. Clenard Childress, Jr., an outspoken African-American abortion critic. "The abortion industry finished what slavery started" by way of targeting and destroying the black race.[142]

In a free economic market in which supply and demand is not regulated or is regulated with only minor restrictions, the U.S. tobacco industry thrived by glamorizing smoking and denying its risks. Costly cigarette advertising targeted youth. The industry banked on the expectation that new generations of smokers would become addicted to its product. It operated profitably beneath the radar of the U.S. Department of Health. Meanwhile, smoking was contributing extensively to damaging public health. Finally in 1999 the federal government filed a racketeering lawsuit against "big tobacco." The suit alleged that the industry had engaged in a fifty-year conspiracy to deceive the public about the dangers of smoking, its addictiveness and the hazards of second-hand smoke. The government prevailed in this landmark case, but not before the tobacco industry had killed untold millions and amassed as much as $280 billion dollars in profits.[143]

A profitable industry will generally survive, at least in the short term, irrespective of any actual or perceived harm it causes, until that harm is made manifest to the general public. This eventually happened in the slavery and tobacco industries. The question is whether or not the fetal parts industry will meet the same fate.

The past half century's ethical debate on using fetal material for commercial purposes has laid the foundation for the more recent debate on the ethics of research and experimentation on human embryos. The arguments advanced and the precedents established in fetal tissue research have been applied to embryonic stem cell research. The operation of the slippery slope is demonstrated by this 2001 letter sent by a group of Nobel Laureates to President George W. Bush in support of destroying human embryos in embryonic stem cell research.

> "For the past thirty-five years many of the common human virus vaccines---such as measles, rubella, hepatitis A, rabies and poliovirus---have been produced in cells derived

[142] C. H. CHILDRESS, JR., "The Dawning of a King's…".

[143] *United States Department of Justice v. Philip Morris USA, Inc., British American Tobacco, Ltd., Council for Tobacco Research USA, Inc.*, 06-5267 (2009).

> from a human fetus to the benefit of tens of millions of Americans. Thus, precedent has been established for the use of fetal tissue that would otherwise be discarded."[144]

President Bush adopted this line of reasoning in allowing embryonic stem cell research to continue on the sixty existing stem-cell lines that were in current scientific use. However, the U.S. Conference of Catholic Bishops deemed the Laureates' analogy invalid. "The federal government is choosing here and now to cooperate with researchers who have destroyed human embryos, and even in some cases to reward them with research grants, since these researchers have the most immediate access to the cell lines thereby created."[145] But already the threshold had been crossed into a brave new world where human life would be indistinguishable from any other raw material.

6.3. Cooperation in Evil

Even for those who view legal abortion as a necessary evil required to insure equality for women, it is difficult to dispute the injustice of the basic act, that of extinguishing a separate human life. Declaring abortion a "right" cannot right the underlying moral wrong, wrote Supreme Court Justice Antonin Scalia, dissenting in *Casey*. "*Roe* created a vast new class of abortion consumers and abortion proponents by eliminating the moral opprobrium that had [previously] attached to the act… If the Constitution guarantees abortion, how can it be bad?"[146]

The *Catechism of the Catholic Church* states its opposition to abortion as an ethical absolute with intensity. "The unalienable right to life of every innocent human individual is a constitutive element of a civil society and its legislation.[147] Since the first century the Church has affirmed the moral evil of every procured abortion… Direct abortion, that is to say, abortion willed either as an end or a means, is gravely contrary to the moral law."[148] The Second Vatican

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[144] K. J. ARROW et al., "Nobel Laureates' Letter to President Bush", *The Washington Post* (22-2-2001), A02.

[145] UNITED STATE CONFERENCE OF CATHOLIC BISHOPS, "Embryonic Stem Cell Research and Vaccines Using Fetal Tissue", *Pro-Life Activities Fact Sheet* (2001), in http://www.usccb.org/prolife/issues/vaccfac2.shtml [2-8-2009].

[146] JUSTICE ANTONIN SCALIA et al., separate opinion in *Planned Parenthood v. Casey* (1992), 995.

[147] *Catechism of the Catholic Church,* ed. Libreria Editrice Vaticana, United States Conference of Catholic Bishops 1994, 2273.

[148] *Ibid.*, 2271.

Council includes abortion among "intrinsically evil" acts, defined as acts which *per se* and in themselves are always seriously wrong by reason of their object. These acts "contaminate those who inflict them more than those who suffer injustice."[149] "The Church's defense of moral absolutes, including the prohibition of abortion, establishes clear boundaries that protect human dignity."[150]

Does financially profiting from the act of abortion render it more seriously evil or does it simply increase the number of people morally implicated on some level? There are obviously different levels of responsibility in the economic structures that have been described. How closely must one be associated with an evil action before guilt is imputed to him? Ethicists have sought to answer these queries by reference to the principles of "cooperation in evil". "Generally, cooperation in evil is understood to mean the action of a person who participates or collaborates in some way in the performance of a morally wrong act by another person, who is the principle agent… In all these modalities, the cooperation can have various degrees."[151]

The Pontifical Academy for Life published "Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses" (the Reflection) in 2005.[152] It explores the moral culpability of the many parties who participate in preparation, marketing and use of these "tainted" vaccines. The philosophic structural framework laid down in the Reflection is instructive for evaluating the moral degree of culpability of those participating in commercial enterprises experimenting on fetal remains obtained through abortion. The boundaries as to when an action is wrong and the extent to which it is wrong are, more often than not, imprecise

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[149]Cf. JOHN PAUL II, Encyc. Let. *Veritatis splendor. Regarding certain fundamental questions of the Church's moral teaching* (6-8-1993), n 80.

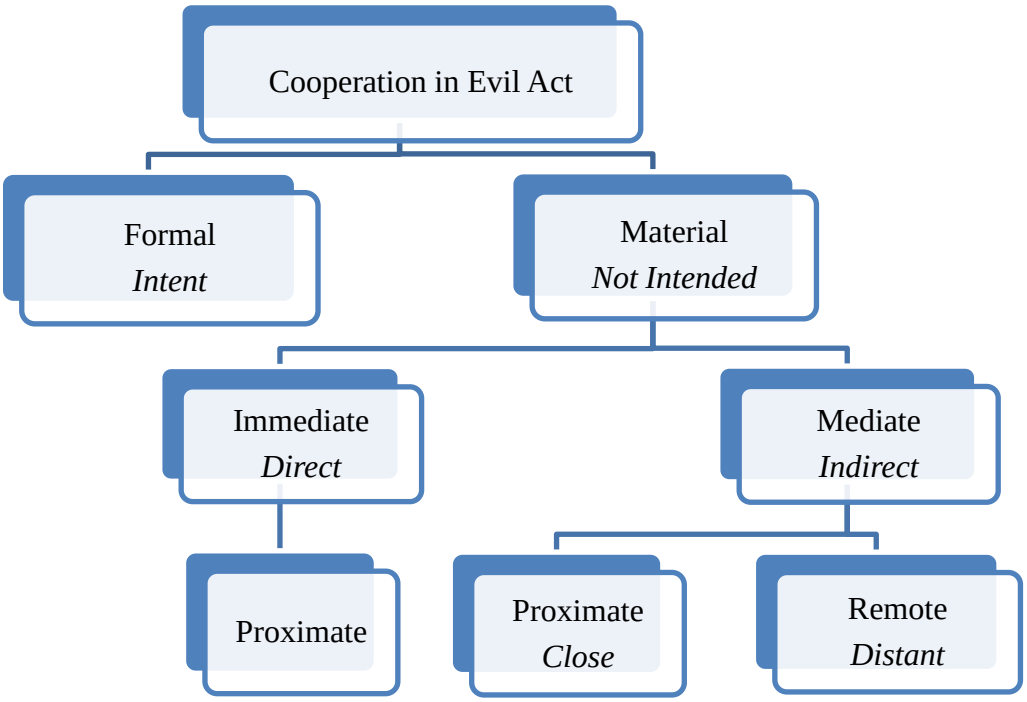
[150]J. F. DESMOND, "How Catholic is This Compass?", *National Catholic Register* (8-11-2009), 7.

[151]A. R. LUNO, "Ethical Reflections on Vaccines Using Cells from Aborted Fetuses", *The National Catholic Bioethics Quarterly* 6/3 (2006), 455.

[152] PONTIFICAL ACADEMY FOR LIFE, "Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses" (2005), reprinted *The National Catholic Bioethics Quarterly* 6/3, 546-547. This moral analysis from the Pontifical Academy for Life was sent by Bishop Elio Sgreccia to Debra Vinnedge on June 9, 2005, based on an earlier study written by Very Rev. Angel Rodriguez Luno. The authors responded to a query about whether parents have a moral obligation to vaccinate their children before admission to school using vaccines derived from aborted human fetuses.

and ambiguous. The Reflection offers guidance in elucidating and clarifying the various levels of cooperation in evil.

The diagram below sets forth this structure visually to facilitate an understanding of the relative position of a particular moral agent in this hierarchy---considering his level of blameworthiness, his degree of involvement, his intent, and his proximity to the original wrong act. A full discussion of the subtleties of the doctrine of cooperation in evil is outside the scope of this paper. However, a straightforward algorithm, even if somewhat one-dimensional, can be illuminating.



> "The first fundamental distinction to be made is that between *formal* and *material cooperation*. *Formal cooperation* is carried out when the moral agent cooperates with the immoral action of another person, sharing in the latter's evil intention… *Formal cooperation* is always morally illicit because it represents a form of direct and intentional participation in the sinful action of another person.
>
> On the other hand, when a moral agent cooperates with the immoral action of another person without sharing his or her evil intention, it is a case of *material cooperation*… *Material cooperation* can sometimes be illicit depending on the conditions.

> *Material cooperation* can be further divided into categories of *immediate* (direct) and *mediate* (indirect), depending on whether the cooperation is in the execution of the sinful action *per se*, or whether the agent acts by fulfilling the conditions… which make it possible to commit the immoral act.
>
> Forms of *proximate cooperation* and *remote cooperation* can be distinguished in relation to the 'distance' (be it in terms of *temporal* space or *material* connection) between the act of cooperation and the sinful act committed by someone else. *Immediate material cooperation* is always *proximate*, while *mediate material cooperation* can be either *proximate* or *remote*… But when *immediate material cooperation* concerns grave attacks on human life, it is always to be considered illicit."[153]

As discussed earlier, vaccine production's initial stages can originate at an abortion site where a fetal-parts wholesaler or broker stands ready to process the fetus for delivery to a researcher or other end-user. If the premise that abortion is an intrinsically evil act is accepted, the actions of the abortive mother and the abortionist amount to *active cooperation* in evil, which is always *formal*.

The wholesaler who cooperates with the performance of the abortion thereby shares the intention and desire to profit from it. He is equally culpable and guilty of *formal cooperation*. The cell line developer may not actively contribute to the actual performance of the abortion, but his association with it is too *proximate* to be morally licit. There is an intimate intersection of the act of abortion and the act of developing the cell line. Thus, he would commit either *formal* or *immediate material cooperation* in evil, depending on the degree of collaboration between the developer and the abortionist.[154]

"Those involved in commercially selling or distributing the cell lines, such as companies in the biotechnology industry, have vested financial interests in the products. The appropriation of the evil of abortion is obvious and occurs on a corporate scale, with several or many individuals involved. The greater the financial gain, the greater the appropriation of the evil act… Grave injustice is involved in reaping profits from such direct by-products of a willful abortion… Also, since there is a demand for products of induced abortion, the company becomes

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[153] PONTIFICAL ACADEMY FOR LIFE, "Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses" (2005), reprinted *The National Catholic Bioethics Quarterly* 6/3, 545-546, (original italics).

[154] Cf. A. WONG, M.D., "The Ethics of HEK…", 483-486.

part of a market force that may encourage more abortions to take place."[155] This approaches *formal cooperation* in abortion.

> "As regards the preparation, distribution, and marketing of vaccines produced as a result of the use of biological material whose origin is connected with cells coming from fetuses voluntarily aborted, such a process is stated, as a matter of principle, morally illicit, because it could contribute in encouraging the performance of other voluntary abortions, with the purpose of the production of such vaccines. Nevertheless, it should be recognized that, within the chain of production-distribution-marketing, the various cooperating agents can have different moral responsibilities.
>
> However, there is another aspect to be considered, and that is the form of *passive material cooperation* which would be carried out by the producers of these vaccines, if they do not denounce and reject publicly the original immoral act (the voluntary abortion), and if they do not dedicate themselves together to research and promote alternative ways, exempt from moral evil, for the production of vaccines for the same infections. Such *passive material cooperation*, if it should occur, is equally illicit."[156]

To the extent people complacently make use of abortion-tainted vaccines (assuming that they do not personally approve of abortion), their culpability with respect to the act of abortion is *remote mediate material cooperation*. With respect to the commercialization of the cell lines, they are guilty of *mediate material cooperation*. As to the marketing of the vaccines, their cooperation is *immediate material cooperation*. On a cultural level, use of these vaccines "contributes in the creation of a generalized social consensus to the operation of the pharmaceutical industries which produce them in an immoral way." How should one judge governmental authorities or national health-care systems which approve and facilitate using the vaccines? Their cooperation in evil is considered even "more intense" than that of the general public.[157]

Finally, what of parents and doctors who must resort to these vaccines for health reasons, especially when there is no ethical alternative? There is a grave duty to use alternative vaccines, if they exist, and to conscientiously object to those having moral problems. There is also a moral duty to fight and employ every lawful means to change unscrupulous and unethical actions of the

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[155]*Ibid.,* 486.
[156]PONTIFICAL ACADEMY FOR LIFE, "Moral Reflections on Vaccines…", 546-547.
[157]Cf. *Ibid*., 547.

pharmaceutical industry with regard to tainted vaccines. If, however, there are no alternate vaccines available and ethically acceptable, and if these vaccines cannot be abstained from without causing harm to the children and indirectly to the population as a whole, the vaccines may be used. This falls under the category of *passive material cooperation*. The duty to avoid this form of cooperation in evil is not obligatory if there is "grave inconvenience" or the existence of a proportionally serious reason; i.e., the danger of spreading the pathological agent.[158]

An additional danger is present. Individuals involved in any of the above actions can become desensitized to the sanctity of life. This is particularly true if one has become accustomed to benefits flowing from the performance of an action that foreseeably but unintentionally results in the death of a human being. If one is profiting from abortion, even remotely, it might be tempting to decide against taking steps to eliminate it. A potentially more serious problem to be faced is an interior one---how to justify profiting from a grave evil already committed by another. The cooperator "might simply develop an elaborate scheme of self-deceiving rationalization."[159]

Direct participants in abortion, fetal parts commodification, and related pharmaceutical and cosmetics industry research and development are cases in point. Habitual participation in immoral acts inevitably leads to personal desensitization, self-deception and rationalization about what it means to be human.

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[158]Cf. *Ibid*., 548.

[159]Cf. M. C. KAVENY, "Appropriation of Evil: Cooperation's Mirror Image", *Theological Studies* 61 (2000), 288-306.

CONCLUSION

Whether contemporary society places absolute or relative value on human life is key to the common good. "The absolute value of the person is the proximate foundation of ethics."[160] Without an anthropology securely grounded in the absolute value of the human person, society unravels. "The traditional Western ethic has always placed great emphasis on the intrinsic worth and equal value of every human life regardless of its stage or condition… and this has been the basis for most of our laws and much of our social policy."[161] But cultural acceptance of abortion is in opposition to, indeed a rejection of, human life as an absolute value.

The Supreme Court's 1992 decision in *Planned Parenthood v. Casey*,[162] which affirmed American society's reliance on the availability of abortion, enshrined personal choice over protection of nascent human life as the ultimate good. Referring to the "right" to abortion, the Court's language demonstrates how widespread moral relativism had become.

> "These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." [163]

The legal ethic of abortion has become the pervasive cultural ethos of abortion, reaching far beyond the immediate abortion participants to tarnish the very industries originally intended to benefit humanity.

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[160]R. LUCAS LUCAS, *Man Incarnate Spirit. A Philosophy of Man Compendium,* Circle Press, Torino 1993, 303.

[161]CALIFORNIA MEDICINE EDITORIAL, "A New Ethic for Medicine and Society", *The Western Journal of Medicine* 113/68 (1970), 67.

[162]*Planned Parenthood of Southeastern Pennsylvania…,* 833.

[163]*Ibid.,* 852. This clause, written by Justice Anthony Kennedy, has become infamously known as "the mystery clause", criticized as having turned constitutional law into New Age musings. The Fourteenth Amendment to the U.S. Constitution guarantees the rights, privileges and immunities of citizenship along with due process and equal protection under the law.

Cardinal Justin Rigali assesses abortion's societal impact with the following words:

> "Abortion is the place where those committed to a conditional and selective vision of human rights have planted their flag in our time. They want to draw lines between the important and unimportant members of society, between persons and 'nonpersons.' In a different time or place the forcing issue might be slavery or racism or anti-Semitism. Today abortion and related issues force us to decide whether we mean what we say in speaking of inalienable human rights, inherent in simply being human."[164]

On a secular level, the fruits of abortion and consequent fetal-parts research also alarm some scientists and technicians, who have issued ethical warnings.

> "There are practices that go on in the silence of the scientific or industrial laboratory that the average citizen does not know about, the true significance of which he would not even be able to comprehend, given that they are very complex and highly specialized. The only ones who know about them and understand them are the other researchers, who therefore have the ethical duty to inform the public about them and oppose them in whatever way possible."[165]

It is important to shine a light on these practices that take place behind closed doors. There are powerful forces conspiring to keep this information from the public and the media with the ostensible conviction that they are protecting a woman's right to choose. However, it is becoming obvious that many ideological groups are being used as pawns by powerful financial interests.

In the papal encyclical *Caritas in Veritate---Charity in Truth*---Benedict XVI calls for a global movement from profits to ethics. He says, "Once profit becomes the exclusive goal, if it is produced by improper means and without the common good as its ultimate end, it risks destroying wealth and creating poverty."[166]

Legal and widespread abortion has made possible a host of clandestine businesses and business practices that thrive under the radar of the American populace. Regulation and transparency would help in reform efforts. However, regulation and transparency are avoided in

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[164] J. RIGALI, "Where do we go from here?", *Respect Life Program* (2009-2010).
[165] A. R. LUNO, "Ethical Reflections on Vaccines…", 457.
[166] BENEDICT XVI, Encyc. Let. *Caritas in veritate. On charity in truth* (29-6-2009), n 21.

many cases because of ideological fears of limiting access to abortion or inviting scrutiny by opposing ideological groups. In some situations where practices are hidden from public view, it is simply a matter of shame. "The truth dwells in the interior man," St. Augustine says. Natural law dictates that there is something exceptional about man. The commercialization of human beings as commodities is contrary to the law written in his heart.

The moral law does indeed have a bearing on the just ordering of society. When morality is excluded from a civil society, the weak and vulnerable are easily exploited for the benefit of the strong and powerful. This is the worst brand of injustice. It deserves to be brought to light and fought.

"There is nothing concealed that will not be revealed, nor secret that will not be known. Therefore, whatever you have said in the darkness will be heard in the light, and what you have whispered behind closed doors will be proclaimed on the house tops."[167]

[167]*Luke* 12:2-3.

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