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The Affordable Care Act and the Medicare Program: The Engines of True Health Reform

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ABSTRACT:

The Patient Protection and Affordable Care Act[1] and its amendments by the Health Care and Education Reconciliation Act of 2010[2] constitute landmark legislation known as the Affordable Care Act (ACA). The ACA has made many changes in the Medicare program as part of comprehensive health reform for the U.S. health care sector. Title III of the ACA pertains to improving the efficiency and quality of health care. Title VI calls for greater program integrity for all federally funded health insurance programs. Collectively, the changes in Medicare in these two titles address the three major problems that the Medicare program has faced since its inception: cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. The policy-making process in the Medicare program is exemplary of the process of "muddling through," as described by the Yale economist Charles E. Lindblom. Nevertheless, these changes may also prepare the Medicare program to be transformed, through several incremental changes in upcoming years, into a single payer system.

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1 Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered titles of the U.S.C.). For an excellent source on Affordable Care Act (ACA) changes to the Medicare program, see Patricia A. Davis, et al., *Medicare Provisions in PPACA (P.L. 111-148)*, CONG. RES. SERV. (Apr. 21, 2010), http://assets.opencrs.com/rpts/11-148_20100421.pdf. *See also* Michael J. DeBoer, *Medicare Coverage Policy and Decision Making, Preventive Services, and Comparative Effectiveness Research Before and After the Affordable Care Act*, 7 J. HEALTH & BIOMEDICAL L. 493 (2011).

2 Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

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INTRODUCTION

The Patient Protection and Affordable Care Act[3] and its amendments by the Health Care and Education Reconciliation Act of 2010[4] together establish the Affordable Care Act (ACA), the health care reform law that will be implemented in full force in 2014. The ACA has made many changes in the Medicare program. These reforms in Medicare address the three major problems facing the Medicare program since its inception: cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. They may also prepare the Medicare program to be transformed into a single payer system should other coverage expansions in the ACA fail.

The provisions of the ACA that will have the greatest impact on the reform of the Medicare program and the health care sector, generally, are in Titles III and VI. Historically, since its inception in 1965, the Medicare program has been at the forefront in crafting strategies to address the major problems of the health care sector with respect to escalating costs and improving quality, as well as preventing and punishing fraud and abuse. State Medicaid programs and private payers are greatly influenced by the policy developments in the Medicare program and often follow Medicare policy. At the very least, then, the ACA reforms in Titles III and VI will be influential in promoting health care reform throughout the health care sector.

However, the possibility exists that the coverage expansions in the ACA will fail and that progress toward universal coverage will stall. In this event, a reformed Medicare program will be in an excellent position to expand into a national single payer system that provides universal coverage. As an all payer system, Medicare would confront the same problems of cost and volume control, value for payment, as well as fraud and abuse. To the extent that the ACA reforms move toward addressing these problems effectively, they enhance the possibility that Medicare will become a strong and sustainable single payer system.

In understanding Medicare and crafting its reform, it is important to appreciate what the Medicare program has accomplished since its inception in 1965.[5] Medicare has assured access to affordable health insurance and health care for elders and the severely disabled. Medicare has also contributed to a

3 Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered titles of the U.S.C.).

4 Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (codified as amended in scattered titles of the U.S.C.).

5 Marilyn Moon, *Medicare Matters: Building on a Record of Accomplishment*, 22 HEALTH CARE FINANCING REV. 9 (2000); *see Medicare at 40: Past Accomplishments and Future Challenges*, AARP (July 2005), http://assets.aarp.org/rgcenter/health/medicare_40.pdf.

vibrant health care sector including highly profitable pharmaceutical and medical device industries. Indeed, the medical device industry leads the world with over half of the medical device manufacturers being located in the United States.[6]

It is important to appreciate the way in which Congress and Medicare policy-makers create policy. Policy-making process in the Medicare program is exemplary of the process of "muddling through," as described by the Yale economist Charles E. Lindblom in his famous article, *The Science of "Muddling Through,"* in 1959.[7] Lindblom describes "muddling through" as an alternative to a formal ideologically driven process of starting with values to be promoted, considering a theory for guidance, and empirically reviewing all options. In the process of "muddling through," a policymaker sets a principal objective, without consideration of values except the most relevant. The policymaker then identifies and compares relatively few policy options without real reference to theory or to other values not immediately relevant and drawing greatly from past experience.[8]

The Medicare policymakers, in both Republican and Democratic administrations, have "muddled through" in making policy that generally, if incrementally, advances the program. Policy alternatives considered are often only those that are politically palatable—at least to political opponents and the provider community. Also, Congress and Medicare policymakers revisit Medicare initiatives annually to advance or reform the initiative. Medicare policymaking, for the most part, focuses on improving the program, while containing costs, placating providers and serving Medicare beneficiaries.

Each year since the program's inception, Congress has made changes in the Medicare program. Generally these changes are made through amendments to the Social Security Act (SSA) or in legislation to reconcile the federal budget. Occasionally, Congress will enact legislation specifically designed to change the Medicare program directly, as was done in 2003 with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[9] Figure 1 lists the annual legislation that has made major changes to the Medicare program.

In the early years of the Medicare program, Congress and the Medicare program would generally focus on each provider and supplier group independently. Further, most major reforms focused on inpatient hospitals under Part A and physician services under Part B. Since the inception of the Medicare program, the largest proportion of expenditures has gone to hospitals and

6 Yair Holtzman, *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUSTRY (July 17, 2012), http://www.mddionline.com/article/medtech-2012-SWOT.

7 *See* Charles E. Lindblom, *The Science of "Muddling Through,"* 19 PUB. ADMIN. REV. 70 (1959).

8 *Id.*

9 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 26 and 42 U.S.C.).

secondarily to physicians and other Part B providers.[10] Since 2000, Congress and policymakers have approached reform in a more integrated fashion. They have proceeded from an understanding that physicians and hospitals were inextricably intertwined in their decisionmaking and Medicare needed to incentivize all providers to work together and coordinate care in an efficient and cost-effective manner.

In making reforms, the Medicare program follows a distinct pattern. First, Congress and policymakers recognize a problem in the program or the health care sector that needs attention. Congress will often assign the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) in statute to prepare a report describing the problem and proposing solutions. Then, if the change is major and requires a statutory modification, Congress often directs CMS to conduct a demonstration to test the contemplated changes.[11] After the evaluation of the demonstration, which takes several years, Congress implements the change in stages with different providers or suppliers. The reforms in the ACA Titles III and VI have been made in the same process. They would likely have been enacted in other legislation, if the ACA had not been enacted in 2010.

The Article proceeds to analyze the ACA Medicare reforms in the following manner. Part I introduces the mission and major themes of the Article. Part II outlines the historic and current challenges that rising Medicare expenditures have posed for the Medicare program. It is important to understand this historical development because the changes to the Medicare program in Titles III and VI of the ACA are, in a very real sense, simply steps in the implementation of reforms already in place. As steps in the implementation of prior reforms, their development is described as much by the policymaking process that Professor Lindblom described. Parts III and IV of this Article outline the detailed changes that Titles III and VI of the ACA made to the Medicare program. Part V of the Article concludes with an assessment of the ACA's potential success. Part V also argues that, with reforms in the ACA, the Medicare program is well positioned to become a national single payer system, should the coverage expansions in the ACA fail.

10 Marian Gornick et al., *Twenty years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, 7 HEALTH CARE FINANCING REV. 13 (Supp. 1985).

11 Charles Fiegl, *Medicare Demonstration Projects: From Idea to Implementation*, AM. MED. NEWS (Nov. 28, 2011), http://www.ama-assn.org/amednews/2011/11/28/gvsa1128.htm.

Figure 1
Federal Legislation Enacting Major Changes in the Medicare Program, 1965-2012

P.L. 89-97, Social Security Amendments of 1965
- Established the Medicare and Medicaid programs
- Established Part A, Hospital Insurance
- Established Part B, Supplementary Medical Insurance

P.L. 90-248, Social Security Amendments of 1967

P.L. 92-603, Social Security Amendments of 1972
- Established the Professional Standards Review Organization (PSRO) Program
- Added Severely Disabled as Medicare Beneficiaries
- Established Medicare Anti-Kickback Authority

P.L. 95-142, Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977

P.L. 95-216, Social Security Amendments of 1977

P.L. 96-499, Omnibus Reconciliation Act of 1980
- Enacted Medicare Secondary Payer Act

P.L. 97-35, Omnibus Budget Reconciliation Act of 1981
- Repealed the PSRO Program.
- Enacted Civil Monetary Penalties Law

P.L. 97-248, Tax Equity and Fiscal Responsibility Act of 1982
- Established the Peer Review Organization Program
- Authorized Medicare HMOs

P.L. 98-21, Social Security Amendments of 1983
- Established Prospective Payment for Inpatient Hospital Care

P.L. 98-369,Deficit Reduction Act of 1984
- Initiated Payment Reform for Physicians

P.L. 99-272, Consolidated Omnibus Budget Reconciliation Act of 1985
- Enacted the Emergency Medical Treatment and Active Labor Act

P.L. 99-509, Omnibus Budget Reconciliation Act of 1986

P.L. 99-562, False Claims Amendments of 1986

P.L. 100-93, Medicare and Medicaid Patient and Program Protection Act of 1987

P.L. 100-203, Omnibus Budget Reconciliation Act of 1987

P.L.104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996
- Enhanced Fraud and Abuse Authorities
- Established Privacy and Security Requirements for Patient medical information

P.L. 105-33, Balanced Budget Act of 1997
- Established the State Children's Health Insurance Program (SCHIP)
- Established Medicare + Choice Program (Part C)
- Established the Medicare Payment Advisory Commission (MEDPAC).
- Established the Sustainable Growth Rate for Medicare physician payment

P.L. 104-113, Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999

P.L.106-554, Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000
- Reformed Medicare Coverage Policy and Decision-making

P.L.108-173, Medicare Prescription Drug, Improvement, and Modernization Act
- Established the Medicare Advantage Program in place of the Medicare + Choice Program (Part C)
- Established the Medicare Prescription Drug Benefit (Part D)
- Established Hospital Inpatient Quality Reporting
- Reformed Medicare Coverage Policy and Decision-making

P.L. 109-171, Deficit Reduction Act of 2005
- Limited Payment for "never events" including "hospital-acquired conditions."

P.L. 109-432,Tax Relief and Health Care Act of 2006
- Established Physician Quality Reporting Initiative

P.L. 110-173Medicare, Medicaid, and SCHIP Extension Act of 2007

P.L. 110-275, Medicare Improvements for Patients and Providers Act of 2008
- Established the Physician Quality Feedback Program

• Established National Standards for Nursing Homes P.L. 100-360 Medicare Catastrophic Coverage Act of 1988 • Established a Catastrophic Coverage benefit under Medicare P.L. 101-234, Medicare Catastrophic Coverage Repeal Act of 1989 P.L. 101-239, Omnibus Budget Reconciliation Act of 1989 • Established Physician Self-Referral Restrictions (Stark I) P.L. 101-508, Omnibus Budget Reconciliation Act of 1990 P.L. 103-66, Omnibus Budget Reconciliation Act of 1993 • Expanded Physician Self-Referral Restrictions (Stark II) P.L.103-432 Social Security Act Amendments of 1994	P.L. 111-5, American Recovery and Reinvestment Act of 2009 • Funded Comparative Effectiveness Research P.L. 111-48, Patient Protection and Affordable Care Act P. L. 111-152, Health Care and Education Reconciliation Act of 2010 • Enacted comprehensive health reform including reforms of the Medicare program P.L. 112-240, American Taxpayer Relief Act of 2012

I. TAMING THE GROWTH IN MEDICARE EXPENDITURES

The Medicare program already is a major source of coverage for a significant portion of the U.S. population. In 2011, Medicare provided insurance for 40.4 million aged 65 or older and 8.3 million disabled for a total of 48.7 million people.[12] Thus, almost one-sixth of the U.S. population depends on the Medicare program. Total Medicare expenditures in 2011 were $549.1 billion.[13] Medicare expenditures constituted 15 percent of total federal outlays in 2010 and over 3 percent of the gross domestic product.[14] By size alone, Medicare is a tremendously important program to millions of people as well as the providers, manufacturers, and suppliers who serve them.

Amending the SSA,[15] Congress established the Medicare program to provide health care coverage for the aged in 1965. Medicare, a federal social insurance program, administered by the CMS, provides insurance for hospital and extended-care services and supplementary medical insurance for physician and

12 Bds. of Trs., *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS 6 (Apr. 23, 2012), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf.

13 *Id.*

14 *Medicare Spending and Financing: A Primer*, KAISER FAMILY FOUNDATION 1-2 (Feb. 2011), http://www.kff.org/medicare/upload/7731-03.pdf.

15 Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 101-111, 121-122, 79 Stat. 286, 291-360 (codified as amended at 42 U.S.C. §§ 1395-1396 (2006)); *see also* S. REP. NO. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943.

associated services to the aged, disabled, and certain individuals with end stage renal disease.[16]

The Medicare program is comprised of four parts. Parts A and B were contained in the original Medicare statute and are called "Fee-for-Service" or "original" Medicare. Part A, Hospital Insurance for the Aged, covers hospital and extended-care services.[17] Part B, Supplementary Medical Insurance, covers physician and other outpatient services.[18] Part C of the Medicare program, now called the Medicare Advantage program (since substantial changes to the program in the MMA[19]), was established in the Balanced Budget Act of 1997.[20] Part C authorizes the provision of Medicare benefits through private health plans and allows private health plans to augment the benefit package as well. Established in the MMA,[21] Part D is a voluntary prescription drug benefit program.

The Medicare program is financed through two trust funds: the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund.[22] The Hospital Insurance Trust Fund, which pays for items and services under Part A and Part A services provided in Medicare Advantage plans under Part C, is funded primarily by a payroll tax.[23] The Supplementary Medical Insurance Trust Fund, which pays for Part B items and services, is funded from premiums under Parts B and D, and, to a minimal extent, from general revenues.[24] This trust fund also pays for Part A and B services provided through Part C Medicare Advantage plans and Part D prescription drug plans.[25]

Table 1 presents the major institutional and professional providers that serve Medicare beneficiaries. The Medicare program also contracts with Medicare Administrative Contractors to manage claims and payment of Medicare Part A

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16 In 1972, Congress added the disabled and individuals with end stage renal disease to those eligible for Medicare. Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463 (1972) (codified as amended at 42 U.S.C. § 1395 (2006)).

17 42 U.S.C. §§ 1395c-1395i (2006).

18 *Id.* §§ 1395j–1395w-5.

19 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, §§ 201-241, 117 Stat. 2066, 2176-2221 (2003) (codified as amended at 42 U.S.C. § 1395 (2006)); *see* Timothy Stoltzfus Jost, *The Most Important Health Care Legislation of the Millennium (So Far): The Medicare Modernization Act*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 437 (2005).

20 Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275 (1997) (codified as amended at 42 U.S.C. § 1395w-21 (2006)).

21 MMA § 101.

22 42 U.S.C. §§ 1395i-1395t (2006).

23 *Id.* § 1395i.

24 *Id.* § 1395t.

25 *Id.* § 1395t(g); *see How is Medicare Funded?*, MEDICARE.GOV, http://www.medicare.gov/about-us/how-medicare-is-funded/medicare-funding.html (last visited Apr. 23, 2013).

and B providers. Under Part C, Medicare Advantage (MA) plans handle payments to Medicare providers.

Individual and aggregate health care expenditures (HCE) are a function of the cost of an item or service multiplied by the volume of items or services. Metaphorically, the function is expressed as follows: HCE = (Cost of Items and Services in Dollars) x (Volume of Items and Services). The unit measures for volume are determined by the manner in which the item or service is delivered, for example, "hospital patient days," "physician visits," or number of items sold. In the early years of the Medicare program, Congress and policymakers focused on reducing the two variables—cost and volume—as both had grown beyond expectations in the early years of the Medicare program.

The seriousness of the cost problem surfaced shortly after the inauguration of the Medicare program and has dominated health policymaking ever since. Congress and HEW almost immediately recognized that the costs of the Medicare program would greatly exceed the initial Medicare cost projections.[26] Figure 2 displays the explosive growth in Medicare expenditures since the inauguration of the program.

26 STAFF OF S. COMM. ON FINANCE, 89TH CONG., PROPOSED MEDICARE REIMBURSEMENT FORMULA, at i (Comm. Print 1966); STAFF OF THE S. COMM. ON FINANCE, 91ST CONG., MEDICARE AND MEDICAID: PROBLEMS, ISSUES, AND ALTERNATIVES 140-43 (Comm. Print 1970).

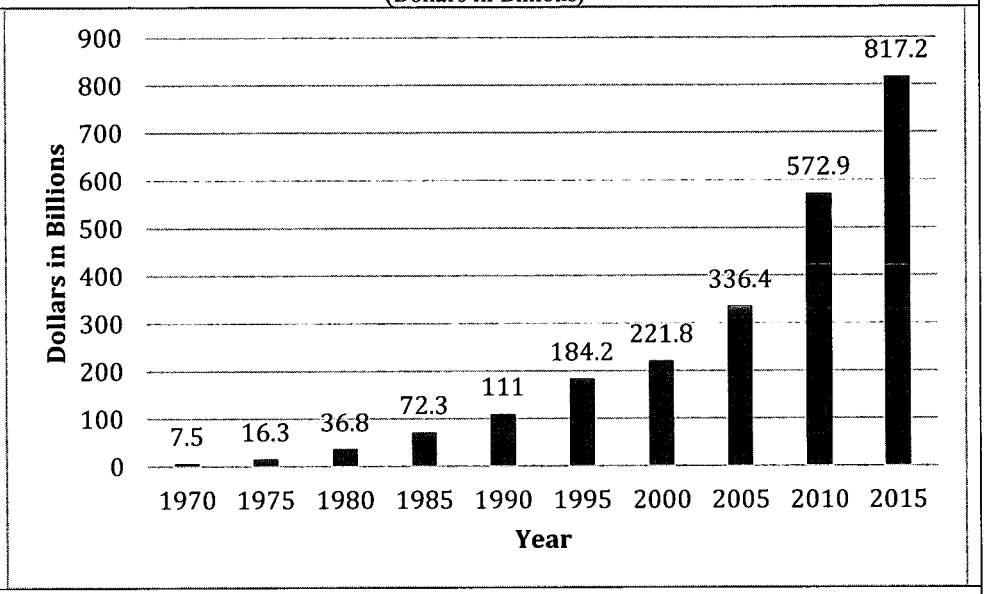
Table 1
The Institutional and Professional Healthcare Providers that Serve Fee-for-Service Medicare Beneficiaries under Parts A and B of the Medicare Program and which also contract with MA plans to serve Medicare Beneficiaries

Providers Paid Under Medicare Part A	**Providers Paid Under Medicare Part B**	
Institutional Providers	**Professional Providers (and their organizations)**	**Suppliers (Selected)**
Hospitals Acute Care Hospitals Psychiatric Hospitals Long Term Care Hospitals Rehabilitation Hospitals	Physicians Nurse Practitioners Physician Assistant Clinical Nurse Specialist Certified Registered Nurse Anesthetist Certified Nurse-Midwife Clinical Social Worker Clinical Psychologist Registered Dietitian/Nutrition Professional Podiatrists	Ambulance Service Suppliers Part B Drug Vendors Portable X-ray Suppliers Intensive Cardiac Rehabilitation Suppliers
Skilled Nursing Facilities Long Term Care Hospitals Rehabilitation Hospitals "Swing Bed" Units in Acute Care Hospitals	**Outpatient Service Providers** Clinic/Group Practices Hospital Outpatient Departments Ambulatory Surgical Centers Mammography Centers Independent Clinical Laboratories Independent Diagnostic Testing Facilities Radiation Therapy Centers	
Home Health Agencies	**Home Health Agencies**	

From the early days of the Medicare program, Congress and the administrations of presidents from both parties sought to reduce the growth in Medicare expenditures. The ostensible premise of the Social Security Amendments of 1965 was that the provider community would supply only reasonable and necessary care and would not respond to financial incentives in the program's reimbursement methodologies to provide excess and unnecessary care or engage in fraud and abuse. However, according to Wilbur Cohen, the Secretary of the Department of Health, Education and Welfare (HEW) when the Medicare program was enacted, "[t]he ideological and political issues between 1960 and 1965 were so dominating that they precluded consideration of issues such as reimbursement alternatives and efficiency options."[27]

27 Wilbur J. Cohen, *Reflections on the Enactment of Medicare and Medicaid*, 7 HEALTH CARE FINANCING REV. 3, 5 (1985).

Figure 2
Growth in Medicare Expenditures, 1970-2015
(Dollars in Billions)



Note: Figures for 2010 and 2015 are projected.
Source: The Commonwealth Fund, Data from 2006 Medicare Trustees' Report

Table 2 presents elements of the Medicare program's regulation of its expenditures. The paramount goal of this regulation is to assure that the program pays only for reasonable and necessary care for Medicare beneficiaries. Table 2 also indicates whether the strategies established to achieve this goal have had an impact on the efficiency of care delivery, the overall cost or volume of Medicare items and services, as well as the quality and effectiveness of care. Over the years, the Medicare program has had to adopt a continuum of regulation to achieve this goal, including strategies to eliminate wasteful and unnecessary care as well as outright fraudulent care that was never provided.

Table 2
Regulatory Goals and Strategies to Regulate the Volume of Medicare Items and Services and the Impact of the Goals and Strategies on the Efficiency of Care Delivery, the Impact on Equation for Medicare Expenditures and the Resulting Characteristic of Care in terms of Quality and Effectiveness

Regulatory Goals	Regulatory Strategies to Achieve Goals	Efficiency Level in the Delivery of Items and Services	Impact on HCE = Cost x Volume Equation	Resulting Character of Care
Achieve Reasonable and Necessary Items and Services	Medicare Coverage Policy Medicare Payment Policies Medicare Quality Measures	Efficient	No Adverse Impact	High Quality, Cost Effective Care
		Inefficient	Impact on Cost Variable	High Quality, High Cost Care
Reduce Arguably Reasonable but Unnecessary Items and Services	Medicare Coverage Policy Medicare Payment Policies Medicare Quality Measures	Efficient	Impact on Volume Variable	Poor Quality, Wasteful Higher Cost Care
		Inefficient	Impact on Cost and Volume Variables	Poorer Quality, Wasteful Higher Cost Care
Eliminate Unreasonable and Unnecessary Items and Services	Medicare Coverage Policy Medicare Payment Policies Medicare Fraud and Abuse Authorities	Efficient	Greater Impact on Cost and Volume Variables	Wasteful and Abusive Care
		Inefficient	Lesser Impact on Cost and Volume Variables	More Wasteful and Abusive Care
Prevent Claims for Items and Services which were not Provided	Medicare Criminal Fraud and Abuse Authorities	Efficient	Greater Impact on Cost and Volume Variables	Fraudulent Care
		Inefficient	Lesser Impact on Cost and Volume Variables	Fraudulent Care

A. The Challenge of Cost Inflation

In 1965, the Medicare program paid hospitals the costs, as calculated by hospitals, of providing services to beneficiaries. The only stipulation was that the costs be "reasonable."[28] Similarly, the Medicare program paid physicians a reasonable charge based on usual and customary charges in the market place.[29] Because both of these reimbursement methodologies placed control over the cost of, and charges for, care in the hands of the providers, providers were able to set

28 Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 296 (codified as amended at 42 U.S.C. §§ 1395(f)(b), 1395x(v) (2006)).

29 *Id.* § 102(a) (codified as amended at 42 U.S.C. § 1395(a) (2006)).

the payment rates for items or services. Not surprisingly, these methods proved very costly, and Medicare expenditures grew at alarming rates immediately upon implementation of the program.[30]

1. Inpatient Hospital Payment

Congress focused initially on hospital costs, as these represented the greatest proportion of Medicare expenditures and were the greatest problem. In the Social Security Amendments of 1972, Congress authorized HEW, the predecessor of HHS, to impose a limit on the routine costs that Medicare paid hospitals.[31] In addition, Congress authorized HEW to conduct demonstrations of different ways Medicare could pay for inpatient hospital and skilled nursing care services.[32] Robert B. Fetter and John D. Thompson of Yale University developed diagnosis related groups (DRGs)[33] as a classification system that groups similar clinical conditions and procedures furnished by the hospital during the stay.[34] HEW tested the DRGs in demonstration project involving all in-patient, acute care hospitals in the state of New Jersey.[35]

In the early 1980s, Congress and the Reagan Administration enacted the Medicare inpatient prospective payment system (IPPS) for hospitals, which used the DRGs developed at Yale and tested in New Jersey. In the Tax Equity and Fiscal Responsibility Act of 1982, Congress laid the groundwork for prospective payments by establishing limits on the costs that Medicare would pay hospitals for each patient case and calling on HHS to develop a legislative proposal for a prospective payment system by December 1982.[36] Following the HHS proposal

30 *See supra* note 27 and accompanying text.

31 Social Security Amendments of 1972, Pub. L. No. 92-603, § 223, 86 Stat. 1329 (codified as amended at 42 U.S.C. § 1395x(v)(1)(A) (2006)).

32 *Id.* § 222 (codified at 42 U.S.C. § 1395b-1 (2006)).

33 John D. Thompson, *The History of the Development of DRGs*, *in* COMPELLED BY DATA: JOHN D. THOMPSON 71 (William D. White ed., 2003); *see also* Robert B. Fetter et al., *A System for Cost and Reimbursement Control in Hospitals*, 49 YALE J. OF BIOLOGY & MED. 123 (1976); John D. Thompson, *DRGs Broaden Hospitals' Accountability, Responsibility*, 62 HOSP. PROGRESS, June 1981, at 46; John D. Thompson et al., *Case Mix Accounting: A New Tool*, *in* SAMUEL LEVEY & THOMAS MCCARTHY, HEALTH MANAGEMENT FOR TOMORROW 157 (1980); John D. Thompson & Robert B. Fetter, *Simulation of Hospital Systems*, 3 OPERATIONS RES. 689 (1965).

34 CENTERS FOR MEDICARE & MEDICAID SERVS. (CMS), *Acute Inpatient PPS*, CMS.GOV (May 3, 2013, 11:00AM), https://www.cms.gov/AcuteInpatientPPS; CMS, *Acute Care Hospital Inpatient Prospective Payment System*, DEP'T OF HEALTH & HUMAN SERVS. (DHHS) (Feb. 2012), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts /downloads/AcutePaymtSysfctsht.pdf (describing DRGs).

35 William C. Hsiao et al., *Lessons of the New Jersey DRG Payment System*, 5 HEALTH AFF., May 1986, at 32.

36 Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 101, 96 Stat. 324, 331-36 (codified as amended at 42 U.S.C. § 1395ww(a)-(c) (2006)).

for a prospective payment system based on DRG's,[37] Congress adopted the IPPS the following spring in the Social Security Amendments of 1983.[38]

Under the IPPS, the Medicare program pays acute care hospitals a fixed price, adjusted for geographic and wage cost differences, for each Medicare case based on the DRG in which the patient's particular condition falls.[39] HHS stated in its mandatory report to Congress on the new payment system:

> The ultimate objective of PPS is to set a reasonable price for a known product. This provides incentives for hospitals to produce the product more efficiently. When PPS is in place, health care providers will be confronted with strong lasting incentives to restrain costs for the first time in Medicare's history.[40]

The Medicare prospective payment system for hospitals has been in place for twenty-seven years. Neither Congress nor the administrations of both parties have fundamentally changed IPPS since its inception in 1983. In 2008, CMS established a new DRG system, the Medical Severity—DRGs (MS-DRGs), to better account for differences in severity for similar conditions.[41] Congress and CMS have extended prospective payment methodologies to nursing homes and other institutional providers.[42]

2. Physician Payment

Also in the Social Security Amendments of 1983, Congress directed the Secretary of HHS to study possible methods of paying physicians according to a

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37 DHHS, HOSPITAL PROSPECTIVE PAYMENT FOR MEDICARE: REPORT TO CONGRESS REQUIRED BY THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982 66 (1983).

38 Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65, 150 (codified as amended at 42 U.S.C. § 1395ww (2006)).

39 42 U.S.C. § 1395ww(d)(1)(2006); Medicare Program; Prospective Payments for Medicare Inpatient Hospital Services (Interim Final Rule), 48 Fed. Reg. 39,752 (Sept. 1, 1983) (codified at 42 C.F.R. pts. 405, 409, 489 (2011)).

40 DHHS, *supra* note 37, at 101.

41 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 23,528 (proposed Apr. 30, 2008) (to be codified as amended at scattered pts. of 42 C.F.R.); *see Acute Inpatient PPS*, CENTERS FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/AcuteInpatientPPS (last updated Apr. 10, 2013); CMS, *Acute Care Hospital Inpatient Prospective Payment System*, DHHS (Feb. 2012), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf.

42 42 U.S.C. § 1395yy (2006) (skilled nursing facilities); *Id.* § 1395fff (home health services); *see* CMS, *Skilled Nursing Prospective Payment System*, DHHS (Oct. 2012), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/snfprospaymtfctsht.pdf.

methodology similar to the IPPS or hospitals.[43] The major reforms of physician payment methods before IPPS included limiting the permissible rate of increase in the prevailing charge to an index that reflected inflation,[44] reforming the payment methods for physicians in teaching hospitals,[45] and tightening the payment methods for hospital-based physicians, such as anesthesiologists, pathologists, and radiologists.[46]

In 1989, Congress enacted a revised payment system for physician services that paid physicians based on the time and resources involved in treating specific conditions rather than on a charge basis.[47] Congress enhanced the system in the Omnibus Budget Reconciliation Act of 1990.[48] In these two pieces of legislation, Congress replaced the charge-based fee schedule with the Resource Based Relative Value Scale (RBRVS).

The RBRVS is based on relative value units (RVUs) for three cost components of medical care—physicians' work effort, physicians' practice expenses, and malpractice liability insurance expenses. These RVUs are then adjusted for geographic differences[49] and a conversion factor designed to curtail the overall increase in Part B expenditures.[50] Dr. William Hsiao, of Harvard University, and his multidisciplinary team developed the RVUs for physicians' work over many years.[51] CMS annually updates the physician work RVUs for new and revised codes based on, in part, recommendations from the American Medical Association's Specialty Society Relative Value Update Committee.[52]

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43 Social Security Amendments of 1983 § 603(a)(2)(B).

44 42 U.S.C. § 1395x (2006).

45 *Id.* § 1395f(g).

46 *Id.* § 1395xx.

47 *Id.* § 1395u(b).

48 Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4101-4118, 104 Stat. 1388 (codified as amended at 42 U.S.C. § 1395 (2006)).

49 42 U.S.C. § 1395w-4(b)(1)(c) (2006).

50 *See infra* notes 54-59 and accompanying text.

51 *See* William C. Hsiao et al., *Estimating Physicians' Work for a Resource-Based Relative-Value Scale*, 319 NEW ENG. J. MED. 835 (1988); William C. Hsiao et al., *The Resource-Based Relative Value Scale: Toward the Development of an Alternative Physician Payment System*, 258 J. AM MED. ASS'N 799 (1987); William C. Hsiao et al., *Resource-Based Relative Values: An Overview*, 260 J. AM MED. ASS'N 2347 (1988); William C. Hsiao et al., *Results and Policy Implications of the Resource-Based Relative-Value Study*, 319 NEW ENG. J. MED. 881 (1988); William C. Hsiao et al., *Results, Potential Effects, and Implementation Issues of the Resource-Based Relative Value Scale*, 260 J. AM MED. ASS'N 2429 (1988); William C. Hsiao & Edmond R. Becker, *Paying Physicians According to their Resource-Costs: The Development of a Resource-Based Relative Value Scale*, 12 HEALTH POL'Y 257 (1989).

52 AMA/Specialty Society, *RVS Update Process*, AM. MED. ASS'N (2007), http://www.ama-assn.org/ama1/pub/upload/mm/380/rvs_booklet_07.pdf.

B. The Challenge of the Burgeoning Volume of Medicare Services

The second challenge of concern to policymakers has been controlling the volume of care for Medicare beneficiaries. The issue of volume is complicated. At a minimum, increases in volume might represent an increase in the number of new beneficiaries receiving services or an increase in the number of services per beneficiary. At some point, increased volume becomes unnecessary and may lead to poor quality care and potentially program abuse. The problem historically for the Medicare program is that, by locating the definition of the content and quality of medical care with the medical profession, stewards of the Medicare program were unable to determine when care was excessive, poor in quality, or abusive. Only with the advances in health services research, discussed in D of this Part, and the empirical demonstration of poor quality and excessive care in statistical terms understandable to non-physician policymakers was the dominance of physicians in defining the content and quality of medical care reduced.

1. Retrospective Utilization Review

The Social Security Amendments of 1965 required hospitals to have utilization review committees as a condition of participation in Medicare.[53] Thus began Medicare's express responsibilities regarding the volume and quality of care of Medicare beneficiaries. The statute did not specify detailed requirements for these programs. However, in March 4, 1969, HEW promulgated a proposed rule requiring that hospitals engage in utilization review of hospital services for the Medicare and Medicaid programs.[54] Later, Congress required hospitals to establish more aggressive internal utilization review programs.[55]

In 1972, Congress established the Professional Standards Review Organization (PSRO) program.[56] This program required the Medicare program to contract with independent physician-dominated organizations to review the utilization of health care services for Medicare beneficiaries. In 1981, the Reagan Administration and Congress repealed the program,[57] apparently in response to concerns from the medical profession about the program's intrusiveness into

53 Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 313 (codified as amended at 42 U.S.C. § 1395x(k) (2006)).

54 Federal Health Insurance for the Aged: Composition of Utilization Review Committees in Hospitals and Extended Care Facilities, 34 Fed. Reg. 16,628 (proposed Oct. 17, 1969) (codified at 20 C.F.R pt. 405).

55 Social Security Amendments of 1972, Pub. L. No. 92-603, § 237(a)(1), 86 Stat. 1329, 1415 (codified as amended at 42 U.S.C. § 1395, 1410-1411 (2006)).

56 *Id.* § 249F (codified as amended at 42 U.S.C. § 1301 (2006)).

57 Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, §§ 2111-2114, 95 Stat. 358, 793-96 (codified as amended at 42 U.S.C. § 1320 (2006)).

medical practice.[58] In 1982, in preparation for the enactment of new hospital prospective payment system, Congress established the Medical Utilization and Quality Control program.[59] This program established Peer Review Organizations (PROs), private physician-led organizations, to review the utilization of services provided to Medicare beneficiaries. By the late 1990s, CMS concluded that retrospective review of PROs and PSROs had not been particularly successful in addressing unnecessary volume in Medicare services or improving quality of care.[60] At that point, CMS determined to refocus the work of PROs to quality improvement.[61]

2. Volume Controls in Physician Payment Methodologies

Since 1972, Congress and the Medicare program have sought to control the overall spending for physician service with the imposition of limits on overall spending. Congress enacted several factors to adjust for increasing volume in Part B items and services.[62] In the Balanced Budget Act of 1997, Congress replaced existing volume controls[63] with the "Sustainable Growth Rate" (SGR) factor.[64] The SGR is applied to individual physician payments to ensure that the overall growth in aggregate physician payments in a given year essentially does not exceed the rate of growth in GDP for that year. The SGR factor has proven very controversial. In recent years, if it had actually been applied to Medicare physician payments, it would have resulted in markedly lower physician payments.[65] Congress has delayed applying the SGR factor to physician payment

58 JONATHAN OBERLANDER, THE POLITICAL LIFE OF MEDICARE 117-20 (2003).

59 42 U.S.C. § 1320c (2006).

60 *See* Anita J. Bhatia et al., *Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement*, 22 HEALTH CARE FINANCING REV., Fall 2000, at 69 (2000); Stephen F. Jencks and Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992); *see also* Claire Snyder & Gerard Anderson, *Do Quality Improvement Organizations Improve the Quality of Hospital Care for Medicare Beneficiaries?* 293 JAMA 2900 (2005).

61 Bhatia et al., *supra* note 60.

62 42 U.S.C. § 1395u (2006); *Id.* § 1395u(b); *see* John Holahan & Stephan Zuckerman, *The Future of Medicare Volume Performance Standards*, 30 INQUIRY 234 (1993); Thomas Rice & Jill Bernstein, *The Medicare Volume Performance Standards: Can They Control Growth in Medicare Services?* 63 MILBANK Q. 295 (1990).

63 Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4502(b), 4503, 111 Stat. 251, 433-34 (codified as amended at 42 U.S.C. §§ 1395w-4(d) to (f) (2006)).

64 *Id.* § 4502(a), 111 Stat. 432 (codified as amended at 42 U.S.C. § 1395w-4(d)(3) (2006)).

65 Comm. on Legislation & Advocacy, *Medicare and the Sustainable Growth Rate*, AM. MED. ASS'N, http://www.ama-assn.org/resources/doc/mss/cola_medicare_pres.pdf (last visited Apr. 22, 2013); Jim Hahn, *Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System*, CONGR. RES. SERVS. (Aug. 6, 2010), http://aging.senate.gov/crs/medicare15.pdf.

since 2008[66] and postponed application of the SGR factor for several years in the future in 2011.[67]

C. The Problem of Fraud and Abuse

A major problem for the Medicare program since its inception has been fraud and abuse by providers, suppliers, and other opportunists. Health care "fraud" exists where there are intentional attempts to wrongfully collect money relating to medical services, while "abuse" exists where actions were inconsistent with acceptable business and medical practices.[68] In 2009, HHS estimated that of the $2 trillion the federal government spent on health care, at least three percent went to fraud.[69]

1. False Claims and Anti-Kickback Prohibitions

Early on in the Medicare program, it was clear that some providers and suppliers were defrauding and abusing the Medicare program through a variety of improper business and criminal practices. In the Social Security Amendments of 1972, Congress enacted the first anti-fraud prohibition for the Medicare and Medicaid programs.[70] This provision essentially prohibited kickbacks and other payments among providers for referrals of patients. As indicated in the House Ways and Means Committee report, Congress sought only to prohibit practices that had "long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the medicare and medicaid [*sic*] programs."[71]

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66 Medicare Improvements for Patients and Providers Act of 2008, Pub L. No. 110-275, § 131 (codified as amended at 42 U.S.C. § 1395w–4(d)(8) (Supp. 2011)).

67 Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, Pub. L. No. 111-192 (to be codified as amended at 42 U.S.C. § 1395w–4(d)); The Physician Payment and Therapy Relief Act of 2010, Pub. L. No. 111-286 (to be codified as amended at 42 U.S.C. § 1395w–4(d)(11)); Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309 (to be codified as amended at 42 U.S.C. § 1395w–4(d)).

68 CMS, *Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, DHHS (Nov. 2012), https://www.cms.gov/MLNProducts/downloads/Fraud_and_Abuse.pdf; T. R. Goldman, *Eliminating Fraud and Abuse*, HEALTH AFF.: HEALTH POL'Y BREIFS (July 31, 2012), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_72.pdf; Jennifer Staman, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, CONGR. RES. SERV. (Aug. 10, 2010), http://www.aging.senate.gov/crs/medicaid20.pdf; *see* Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241 (2004).

69 *Catch Me If You Can: Solutions to Stop Medicare and Medicaid Fraud from Hurting Seniors and Taxpayers: Hearing Before the S. Special Comm. on Aging*, 111th Cong. 35 (2009) (statement of Daniel R. Levinson, Inspector Gen., U.S. Department of Health and Human Services).

70 Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b)-(c), 278(b)(9), 86 Stat. 1329, 1419, 1454 (codified as amended at 42 U.S.C. §§ 1320a-7b, 1395nn (2006)).

71 H.R. Rep. No. 92-231 at 107-08 (1971).

Congress expanded these fraud and abuse provisions in the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977.[72] These amendments accorded the newly-established Office of the Inspector General (OIG) within HHS-expanded authority to identify and eliminate waste, fraud, and abuse in the department.

The anti-kickback prohibitions have created an extensive regulatory regime over the way in which health care providers do business with one another. While kickbacks are illegal or unethical in many other businesses,[73] the Medicare statute and its interpretations have been much stricter in defining kickbacks and have even proscribed splitting fees that are common in other professions. The Medicare anti-kickback prohibitions seek to limit entrepreneurial behavior on the part of providers to generate business.

In 1981, Congress enacted the Civil Monetary Penalties Act (CMPA) as part of the Omnibus Budget Reconciliation Act of 1981.[74] This law authorized the OIG to impose penalties on violators without having to refer cases to the U.S. Department of Justice. This authority greatly facilitated the Medicare program's ability to go after false claims because the enhanced authority of the OIG to impose penalties and sanctions.

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72 Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95–142, 91 Stat. 1175 (1977) (codified as amended at 42 U.S.C. §§ 1320a, 1396k); *see* Theodore McDowell, *The Medicare and Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691 (1987).

73 The Legal Information Institute at Cornell University Law School defines kickback generally:

> A "kickback" is a term used to refer to a misappropriation of funds that enriches a person of power or influence who uses the power or influence to make a different individual, organization, or company richer. Often, kickbacks result from a corrupt bidding scheme. Through corrupt bidding, the official can award the contract to a company, even though the company did not place the lowest bid. The company profits by having been awarded the bid and getting to perform the contract. In exchange for this corrupt practice, the company pays the official a portion of the profits. This portion is the "kickback." Such a practice falls within a sphere of practices often referred to as "anti-competitive practices." Organized crime has been traced using kickbacks for many years. Some also consider kickbacks to be a type of bribery.

Legal Info. Inst., *KICKBACKS*, CORNELL U. SCHOOL OF L., http://www.law.cornell.edu/wex/kickbacks (last visited Apr. 22, 2013).

74 Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2105(a), 95 Stat. 357, 789 (codified as amended at 42 U.S.C. § 1320a–7a (2006)); *see* Richard P. Kusserow, *Civil Money Penalties Law of 1981: A New Effort to Confront Fraud and Abuse in Federal Health Care Programs*, 58 NOTRE DAME L. REV. 985 (1983).

In the False Claims Act Amendments of 1986,[75] Congress strengthened the False Claims Act (FCA) to make clear that the FCA applied to claims against the Medicare and Medicaid programs. These amendments opened a new front on Medicare defrauders and abusers, by facilitating the ability of private parties, who are often internal whistle blowers that witnessed the fraud and abuse, to bring suit as "relaters" on the government's behalf under the FCA. As a result, the federal government has been able to recover millions of dollars from health care providers under the FCA since the late 1980s.[76]

The Medicare and Medicaid Patient and Program Protection Act of 1987 provided new authority to the OIG to exclude persons or entities from participation in Medicare if the party engaged in a prohibited remuneration scheme.[77] This Act also established alternative civil remedies that would facilitate the regulation of abusive business practices.[78]

In the mid-1990s, Congress added significant provisions to the Medicare fraud and abuse armamentarium. In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress greatly strengthened and coordinated Medicare fraud and abuse authorities.[79] Specifically, HIPAA created a new crime of health care fraud,[80] which includes theft, embezzlement, false statements, obstruction of a criminal investigation, and money laundering, among others.[81] HIPAA also enhanced administrative enforcement mechanisms, and strengthened provisions for exclusion from Medicare participation for offenders.[82] In addition, HIPAA greatly increased penalties under the CMPA.[83] HIPPA also established the national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements in which no findings of liability are made) against health care providers, suppliers, or practitioners.[84]

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75 False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729-3733 (2006)).

76 Thomas H. Stanton, *Fraud-And-Abuse Enforcement In Medicare: Finding Middle Ground*, 20 HEALTH AFF., July-Aug. 2001, at 28.

77 Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680 (codified as amended at scattered sections of 42 U.S.C.).

78 *See* Office of the Inspector Gen., *Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs* DHHS (Sept. 1999), http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm.

79 Health Insurance Portability and Accountability Act of 1996 (HIPPA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended at scattered titles of the U.S.C.); *see* David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 9 (2002).

80 HIPAA § 242.

81 *Id.* §§ 241-250.

82 *Id.* §§ 211-218.

83 *Id.* §§ 231-232.

84 *Id.* § 221.

HIPAA also created three distinct new programs with designated funding streams: the Fraud and Abuse Control Program, the Medicare Integrity Program, and the Beneficiary Incentive Program. The Fraud and Abuse Control Program is jointly administered by the Attorney General and the Secretary of HHS and coordinates fraud control work throughout the government.[85] Pursuant to the Medicare Integrity Program, HHS contracts with private companies to perform fraud control functions in which fiscal intermediaries and carriers had historically shown little interest.[86] Finally, the Beneficiary Incentives Program offers incentive payments to beneficiaries who provide information that lead to monetary recoveries.[87]

2. Physician Self-Referral Prohibition

In 1989, Congress enacted fraud and abuse legislation targeted at addressing physician referrals to clinical laboratories that the physicians owned.[88] There had been much controversy and commentary about the growing practice of physicians of referring patients to their own service providers.[89] In response, Congress, in the Omnibus Budget Reconciliation Act of 1993, expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid.[90] This legislation, known as "Stark II," also contained clarifications and modifications to the exceptions in the original law.

The Medicare statute includes the so-called whole hospital exception to the physician self-referral prohibitions.[91] This exception has become controversial in recent years with the emergence of physician-owned specialty hospitals in many states. In the late 1990s, physicians began building and investing in medical specialty hospitals that were independent of community hospitals in highly lucrative specialties such as cardiology and orthopedics. Physicians, who had

85 *Id.* § 201.

86 *Id.* § 202; *see* Hyman, *supra* note 79.

87 HIPAA § 203.

88 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236-43 (codified as amended at 42 U.S.C. § 1395nn (2006)); *see* Jennifer O'Sullivan, *Medicare: Physician Self-Referral ("Stark I and II")*, CONGR. RES. SERVS. (Sept. 27, 2007), http://aging.senate.gov/crs/medicare19.pdf; *History of the Stark Law*, U.S. LEGAL, http://starklaws.uslegal.com/history-of-stark-law (last visited Apr. 10, 2013).

89 *See, e.g.*, David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Setting the Limits on Physicians' Entrepreneurship*, 320 NEW ENG. J. MED. 1275 (1989); MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST (1995).

90 Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562(a), 107 Stat. 312, 596 (codified as amended at 42 U.S.C. § 1395nn (2006)).

91 42 U.S.C. § 1395nn(d)(3) (2006); *see* CMS, *MLN Matters No. MM3036, MMA-Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals*, DHHS (Mar. 2004), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLN MattersArticles/Downloads/MM3036.pdf.

been tussling with community hospitals and managed care companies throughout the 1990s to get their perceived fair share of patient revenue, moved toward specialty hospitals to gain greater corporate and financial control.[92] Their advent was very controversial, especially for community hospitals, which lost lucrative services and procedures to specialty hospitals.[93]

The rise of physician-owned specialty hospitals raised concerns among policymakers. In 2003, the U.S. General Accounting Office (now the U.S. Government Accountability Office (GAO)) conducted two studies of these emerging developments and raised concerns about their profitability vis-à-vis not-for-profit hospitals and other matters.[94] In the MMA of 2003,[95] Congress imposed an eighteen month moratorium on the whole hospital exception for new specialty hospitals in the physician self-referral prohibitions and directed the Medicare Payment Advisory Committee (MEDPAC), established as an official body to advise Congress on Medicare payment issues in 1997,[96] to study and report on physician-owned medical specialty hospitals.

The MEDPAC conducted a study and gave some remarkable recommendations about the future treatment of physician-owned specialty hospitals.[97] The conclusions of MEDPAC were mixed, reflecting external studies of specialty hospitals.[98] MEDPAC concluded:

> We found that physicians may establish physician-owned specialty hospitals to gain greater control over how the hospital

92 Ron Winslow, *Fed-Up Cardiologists Invest in Own Hospital: They'll Regain Autonomy but Critics See a Grab for More Profitable Care*, WALL ST. J., June 22, 1999, at A1.

93 Rebecca Voelker, *Specialty Hospitals Generate Revenue and Controversy*, 289 JAMA 409 (2003).

94 U.S. GEN. ACCOUNTING OFFICE, GAO-03-683R, SPECIALTY HOSPITALS: INFORMATION ON NATIONAL MARKET SHARE, PHYSICIAN OWNERSHIP, AND PATIENTS SERVED (2003); U.S. GEN. ACCOUNTING OFFICE, GAO-04-167, SPECIALTY HOSPITALS: GEOGRAPHIC LOCATION, SERVICES PROVIDED, AND FINANCIAL PERFORMANCE (2003).

95 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295 (codified at 42 U.S.C. § 1395nn(d)(3) (2006)).

96 Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4022, 111 Stat. 251, 350 (codified at 42 U.S.C. § 1395b-6) (2006)).

97 *Report to Congress: Physician-Owned Specialty Hospitals*, MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC) (Mar. 2005), http://www.medpac.gov/documents/Mar05_SpecHospitals.pdf.

98 Lawrence P. Casalino et al., *Focused Factories? Physician-Owned Specialty Facilities*, 22 HEALTH AFF., Nov. 2003, at 56; Jeff Goldsmith, *Technology and the Boundaries of the Hospital: Three Emerging Technologies*, 23 HEALTH AFF., Nov. 2004, at 149; Leslie Greenwald et al., *Specialty Versus Community Hospitals: Referrals, Quality, and Community Benefits*, 25 HEALTH AFF., Jan. 2006, at 106; David N. Heard, Jr., *The Specialty Hospital Debate: The Difficulty of Promoting Fair Competition Without Stifling Efficiency*, 6 HOUS. J. HEALTH L. & POL'Y 215 (2005); John K. Iglehart, *The Emergence of Physician-Owned Specialty Hospitals*, 352 NEW ENG. J. MED. 78 (2005).

> is run, to increase their productivity, and to provide greater satisfaction for them and their patients. They may also be motivated by the financial rewards, some of which derive from inaccuracies in the Medicare payment system.[99]

In 2005, MEDPAC recommended addressing "inaccuracies, which result in the system paying too much for some DRGs relative to others and too much for patients with relatively less severe conditions."[100] Such reforms would make competition between community hospitals and specialty hospitals more equitable. As noted above,[101] CMS changed the DRG system to the MS-DRG system to address these concerns. MEDPAC also recommended promoting gainsharing to align physician and hospital incentives to allow physicians and hospitals "to share savings from more efficient practices and might serve as an alternative to direct physician ownership."[102]

In 2006, MEDPAC revisited physician-owned specialty hospitals and reported on its empirical study of physician-owned specialty hospitals.[103] In general, the study found that in communities with physician-owned specialty hospitals, rates of cardiac and other procedures were a little higher, but that community hospitals seemed able to maintain financial stability.[104] MEDPAC offered no recommendations on further policy action regarding these hospitals.

D. Medicare and Healthcare Quality

The initial approach of the Medicare program toward assuring quality of care for Medicare beneficiaries was focused mainly on required licensure or accreditation of health care providers.[105] Physicians, hospitals, and other providers were responsible for quality assurance and improvements. Indeed, Title II of the Social Security Amendments of 1965 pertains to Medicare's mention the word "quality" only once in connection with the responsibilities of state agencies in managing survey and certification responsibility for facilities participating in Medicare.[106] In the 1980s, spurred on by health services research indicating that little was known about whether expensive medical procedures were more

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99 MEDPAC, *supra* note 97, at vii.

100 *Id.*

101 *See supra* note 41 and accompanying text.

102 MEDPAC, *supra* note 97, at viii.

103 *Report to Congress: Physician-Owned Specialty Hospitals Revisited*, MEDPAC (Aug. 2006), http://www.medpac.gov/documents/Aug06_specialtyhospital_mandated_report.pdf.

104 *Id.*

105 *See Eleanor D. Kinney, The Affordable Care Act and the Medicare Program: Linking Medicare Payment to Quality Performance*, 67 N.Y.U. ANN. SURV. AM. L. (forthcoming 2012).

106 Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 326 (codified as amended at 42 U.S.C. § 1395aa (2006)).

efficacious than less expensive treatment approaches, medical researchers and third party payers promoted outcome measures as the appropriate indicators of quality in quality assurance and improvement activities.[107] Health services researchers demonstrated that not all costly medical procedures were more effective than less costly care.[108]

Extensive health services research shaped the future of quality science in medicine and paved the way for reforms that reduced volume and improved quality. For health services, research produced empirical evidence on high quality and appropriate health care services in a form comprehensible to non-physicians. First, the work of Dr. John Wennberg and his colleagues demonstrated sharp variation in services provided to Medicare beneficiaries among different geographic areas for the same conditions.[109] The finding dramatically documented provider induced demand for services and the resulting inefficiencies and provision of health care.

A second important development was the application of the theories of Total Quality Management (TQM) and Continuous Quality Improvement (CQI), developed by William E. Deming and Joseph Juran,[110] to health care institutions.[111] According to TQM/CQI theory, quality management should strive to reduce statistical variation in products and production to a level that is uniform and predictable, and also meets the expectations of the customer. Since the

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107 ROBERT H. BROOK ET AL., QUALITY OF MEDICAL CARE ASSESSMENT USING OUTCOME MEASURES: AN OVERVIEW OF THE METHOD (1976); Robert H. Brook & Kathleen N. Lohr, *Monitoring Quality of Care in the Medicare Program*, 258 JAMA 3138 (1987); Paul M. Ellwood, *Shattuck Lecture, Outcomes Management: A Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549 (1988).

108 *See, e.g.*, Robert H. Brook & Kathleen N. Lohr, *Efficacy, Effectiveness, Variations, and Quality: Boundary-Crossing Research*, 23 MED. CARE 710 (1985); David M. Eddy, *Variation in Physician Practice: The Role of Uncertainty*, 3 HEALTH AFF., May 1984 at 74; David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, 7 HEALTH AFF., Feb. 1988, at 19.

109 John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. & MED. 811 (1982); John E. Wennberg & Alan Gittelsohn, *Small Area Variation in Health Care Delivery*, 182 SCIENCE 1102 (1973); John E. Wennberg & Alan Gittelsohn, *Variations in Medical Care Among Small Areas*, 246 SCI. AM., Apr. 1982, at 120.

110 W. EDWARDS DEMING, OUT OF THE CRISIS (1986); W. EDWARD DEMING, THE NEW ECONOMICS (1993); J.M. JURAN, JURAN ON LEADERSHIP FOR QUALITY: AN EXECUTIVE HANDBOOK (1989); J.M. JURAN, MANAGERIAL BREAKTHROUGH: A NEW CONCEPT OF THE MANAGER'S JOB (1964).

111 DONALD M. BERWICK ET AL., CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT (1990); Donald M. Berwick, *Continuous Improvement as an Ideal in Health Care*, 320 NEW ENG. J. MED. 53 (1989); Glenn Laffel & David Blumenthal, *The Case for Using Industrial Quality Control Management Science in Health Care Organizations*, 262 JAMA 2869 (1989).

1990s, data-driven TQM/CQI theory and practice has become an integral part of quality assurance and improvement concepts in the health care field.[112]

A third critical development was the patient safety movement inspired by the Institute of Medicine's (IOM) report, *To Err Is Human*.[113] This report made two factual findings that were so ground-breaking that they precipitated a revolution in U.S. health care: (1) an estimated 44,000 to 98,000 people die each year in hospitals from medical injury; and (2) systems failures, rather than poor performance by individual practitioners, cause at least half of patient injuries.[114] The IOM report recommended that providers create a culture of safety in institutions by borrowing from quality science in the engineering industries.[115] Providers were largely persuaded by these findings and instituted data driven strategies to reduce risks to patient safety.[116]

In 2001, CMS began launching quality initiatives "to assure quality health care for all Americans through accountability and public disclosure."[117] CMS established the Health Care Quality Improvement Initiative (HCQII) to move from addressing individual clinical errors to helping providers improve care generally.[118] In 2002, hospital associations, employers, payers, consumer organizations, the Joint Commission and also CMS established the Hospital Quality Alliance to make "meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality."[119]

In July 2003, CMS launched the National Voluntary Hospital Reporting Initiative. This initiative is now known as the "Hospital Quality Alliance: Improving Care through Information," which is a public-private collaboration to improve the quality of care provided by the nation's hospitals by measuring and

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112 ELLEN MARSZALEK-GAUCHER & RICHARD J. COFFEY, TRANSFORMING HEALTHCARE ORGANIZATIONS: HOW TO ACHIEVE AND SUSTAIN ORGANIZATIONAL EXCELLENCE (1990); CURTIS P. MCLAUGHLIN & ARNOLD D. KALUZNY, CONTINUOUS QUALITY IMPROVEMENT IN HEALTH CARE: THEORY, IMPLEMENTATIONS, AND APPLICATIONS (3rd ed. 2006).

113 INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM (Linda T. Kohn et al. eds., 2000).

114 *Id.*

115 *Id.*

116 INST. OF MED., PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE (Philip Apsden et al. eds., 2004).

117 CMS, *Quality Initiatives—General Information*, CMS, https://www.cms.gov/qualityinitiativesgeninfo, CMS.GOV (Apr. 12, 2013).

118 Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992).

119 HOSPITAL QUALITY ALLIANCE, http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1121785350618 (last visited Jun. 2, 2013).

publicly reporting on that care.[120] In CMS' Hospital Quality Initiative, CMS works with the HQA and other key stakeholders with the support of Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum (NQF), and the Joint Commission, among other organizations.[121] Through this initiative, CMS developed a standardized set of hospital quality measures for use in voluntary public reporting. As part of this initiative, CMS has launched the website, *Hospital Compare*, to provide information on the comparative performance of hospitals on health care quality.[122]

The MMA of 2003 established the Hospital Inpatient Quality Reporting program.[123] Since 2003, CMS has been moving forward with value-based purchasing first for inpatient, acute care hospitals and then for other institutional providers.[124] The Deficit Reduction Act of 2005 (DRA) authorized the launch of the value-based purchasing program.[125] DRA required a reduction by two percent of the applicable percentage increase in payment for covered hospitals that do not submit quality data in a form and manner and by a time specified by the Secretary of HHS.[126] The DRA called for the Secretary to develop a plan for the hospital value-based purchasing program which would begin in FY 2009.[127] In 2007, CMS submitted this plan to Congress.[128] In the FY 2007 final rule for the inpatient prospective payment system, CMS implemented this reduction requirement for deficient quality reporting.[129]

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120 CMS, *Roadmap for Implementing Value Driven Healthcare in the Traditional Medicare Fee-for-Senate Program*, DHHS (Jan. 2009), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads//VBPRoadmap_OEA_1-16_508.pdf.

121 *Hospital Quality Initiative Overview*, CMS (July 2008), https://www.cms.gov/hospitalqualityinits/downloads/HospitalOverview.pdf.

122 *Hospital Compare*, MEDICARE.GOV, http://www.medicare.gov/hospitalcompare (last visited Apr. 10, 2013).

123 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108–173, § 501(b), 117 Stat. 2066, 2289 (codified as amended at 42 U.S.C. § 1395ww (2006)).

124 CMS, *supra* note 120.

125 Deficit Reduction Act (DRA) of 2005, Pub. L. No. 109-171, § 5001(a), 120 Stat. 4, 28 (codified as amended at 42 U.S.C. § 1395ww (2006)).

126 *Id.*

127 *Id.*

128 CMS, *Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program*, DHHS (Nov. 2007), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf.

129 Prospective Payment Systems for Inpatient Hospital Services, 42 C.F.R. pt. 412; *see* Christopher P. Tompkins et al., *Measuring Outcomes and Efficiency in Medicare Value-Based Purchasing*, 28 HEALTH AFF., Jan. 2009, at w251.

A very important step in the development of value-based purchasing was the Premier Hospital Incentive demonstration initiated in 2003.[130] This Demonstration was conducted in partnership with the Premier Healthcare Alliance, a national health care performance improvement organization, and tested whether paying hospitals for performance on various quality metrics would shift performance upward.[131] In evaluation results announced in 2010,[132] participating hospitals improved performance across the board.[133] Subsequent research findings suggest that the actual impact of the value-based purchasing initiative may not have a great effect on Medicare payment to either high or low performing hospitals.[134]

In 2006, Congress turned to quality reporting for physicians. In the Tax Relief and Health Care Act of 2006, Congress established a quality reporting program—the Physician Quality Reporting Initiative (PQRI)—for physicians and other eligible professionals.[135] The Medicare Improvements for Patients and

130 CMS, *Premier Hospital Quality Incentive Demonstration*, CMS.GOV (Apr. 23, 2013, 1:00PM), http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalPremier.html.

131 CMS, *Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care: Fact Sheet*, DHHS (Dec. 2011), http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalPremierPressRelease-FactSheet.pdf.

132 CMS, *Medicare Demonstrations Illustrate Benefits in Paying for Quality Health Care*, MED. NEWS TODAY (Dec. 13, 2010), http://www.medicalnewstoday.com/releases/211115.php.

133 *See* 1 & 2 STEPHEN KENNEDY ET AL., EVALUATION OF THE PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION: IMPACTS ON QUALITY, MEDICARE REIMBURSEMENTS, AND MEDICARE LENGTHS OF STAY (2008); Div. of Research on Traditional Medicare, Evaluation of the Premier Hospital Quality Incentive Demonstration–Executive Summary: Impacts on Quality of Care, Medicare Reimbursements, and Medicare Beneficiaries' Length of Stay during the First Three Years of the Demonstration, CMS (Mar. 3, 2009), https://www.cms.gov/reports/downloads/Premier_ExecSum_2010.pdf; *see also* New Directions for Policy, *Theory and Reality of Value-Based Purchasing: Lessons from the Pioneer*, AGENCY FOR HEALTHCARE RES. & QUALITY (Nov. 2007), http://www.ahrq.gov/qual/meyerrpt.htm.

134 Rachel M. Werner & R. Adams Dudley, *Medicare's New Hospital Value-Based Purchasing Program Is Likely to Have Only a Small Impact on Hospital Payments*, 31 HEALTH AFF., Sept. 2012, at 1932.

135 Tax Relief and Health Care Act of 2006 (TRHCA), Pub. L. No. 109-432, Div. B § 101, 120 Stat. 2922, 2975 (codified as amended at 42 U.S.C. § 1395w-4 (Supp. 2011); *see* CMS, *Physician Quality Reporting System*, CMS.GOV (Apr. 3, 2013, 2:00PM), https://www.cms.gov/PQRS.

Providers Act of 2008 made the PQRI permanent.[136] This act also initiated Physician Feedback Reporting.[137]

The DRA also established a formal role for the National Quality Forum (NQF), which proved a very important development in quality reporting and payment reform. NQF is a nonprofit organization with a mission "to improve quality of American health care by: (1) building consensus on national priorities and goals for performance improvement and working in partnership to achieve them; (2) endorsing national consensus standards for measuring and publicly reporting on performance; and (3) promoting the attainment of national goals through education and outreach programs."[138]

The membership of NQF is diverse and includes a wide variety of health care stakeholders, including consumer organizations, public and private purchasers, physicians, nurses, hospitals, accrediting and certifying bodies, supporting industries, and health care research and quality improvement organizations.[139] As NQF asserts, "NQF's unique structure enables private- and public-sector stakeholders to work together to craft and implement cross-cutting solutions to drive continuous quality improvement in the American healthcare system."[140]

The Medicare Improvements for Patients and Providers Act of 2008 required the Secretary to contract with a consensus-based entity, "such as the National Quality Forum," regarding performance measurement.[141] The central duty of this consensus-based entity is to "synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings."[142] The entity also has to be a private nonprofit organization with a board of designated representatives of stakeholders such as insurers, providers and consumers. The entity's membership must include people with experience in urban health care issues, safety net health care issues, rural and frontier health care issues, and health care quality and safety issues. The entity must conduct its business in an open, transparent manner and provide the opportunity for public comment on its

136 Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 131(b)(1), 122 Stat. 2494, 2521-22 (codified as amended at 42 U.S.C. § 1395w–4(k)(2) (Supp. 2011)); *see* Jonah Stulberg, *The Physician Quality Reporting Initiative–A Gateway to Pay for Performance: What Every Health Care Professional Should Know*, 17 QUALITY MGMT. IN HEALTH CARE 2 (2008).

137 Medicare Improvements for Patients and Providers Act of 2008 § 131(c) (codified as amended at 42 U.S.C. § 1395w–4(n)(1) (Supp. 2011)).

138 *About NQF*, NAT'L QUALITY F., http://www.qualityforum.org/About_NQF/About_NQF .aspx (last visited Apr. 22, 2013).

139 *Id.*

140 *Id.*

141 Medicare Improvements for Patients and Providers Act of 2008 § 183 (codified as amended at 42 U.S.C. § 1395aaa (a) (Supp. 2011)).

142 *Id.*

activities. Finally, the entity has to have at least four years of experience in establishing national consensus standards.

CMS awarded the contract to NQF to serve as the "consensus-based entity." NQF has specific responsibility regarding the endorsement of measures. Regarding endorsements of measures, the entity must consider whether a measure meets the following criteria. First, the measure is "evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level."[143] Second, the measure is "consistent across types of health care providers, including hospitals and physicians."[144]

In addition, the entity is required to maintain and update measures,[145] promote the development of electronic health records,[146] and make reports to Congress. [147] Finally, in more recent years, there has been great interest in comparative effectiveness research as a tool to reduce health care expenditures.[148] In 2009, the American Recovery and Reinvestment Act (ARRA) launched a major research initiative on comparative effectiveness research.[149] The ARRA also called on the IOM to develop national priorities for comparative effectiveness research for this initiative.[150] In 2009, the IOM published national priorities for research that have been the basis of the comparative effectiveness

143 *Id.*

144 42 U.S.C. § 1395aaa (b)(1)(B)(2) (Supp. 2011).

145 *Id.* § 1395aaa (b)(1)(B)(3).

146 *Id.* § 1395aaa (b)(1)(B)(4).

147 *Id.* § 1395aaa (b)(1)(B)(5).

148 *Pub. No. 2975, Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role*, CONG. BUDGET OFFICE (Dec. 2007), http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf; Patrick H. Conway & Carolyn Clancy, *Charting a Path From Comparative Effectiveness Funding to Improved Patient-Centered Health Care*, 303 JAMA 985 (2010); Richard K. Murray & Newell E. McElwee, *Comparative Effectiveness Research: Critically Intertwined with Health Care Reform and the Future of Biomedical Innovation*, 170 ARCHIVES OF INTERNAL MED. 596 (2010); Harold Sox, *Comparative Effectiveness Research: A Progress Report*, 153 ANNALS OF INTERNAL MED. 469 (2010); Gail R. Wilensky, *The Policies and Politics of Creating a Comparative Clinical Effectiveness Research Center*, 28 HEALTH AFF., July-Aug. 2009, at w719; *see* Eleanor D. Kinney, *Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J. L. & MED. 522 (2011).

149 American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 804, 123 Stat. 115, 187 (codified at 42 U.S.C. § 299b-8 (Supp. 2011)).

150 *Id.*; *see* John K. Iglehart, *Prioritizing Comparative-Effectiveness Research—IOM Recommendations*, 361 NEW ENG. J. MED. 325 (2009); Harold C. Sox & Sidney Greenfield, *Comparative Effectiveness Research: A Report from the Institute of Medicine*, 153 ANNALS OF INTERNAL MED. 203 (2009).

research initiative in the ACA.[151] Whether comparative effectiveness research will have the impact warranted by the federal investment remains unclear.[152]

II. IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE (TITLE III)

The reforms in Title III of the ACA are intended to improve the quality and efficiency of health care. In reality, the reforms are targeted at the Medicare program. Table 3 lists all of the subtitles in Title III that pertain to the Medicare program.

A. Transforming the Health Care Delivery System (Subtitle A)

The reforms in Subtitle A have two common goals. The first is to link Medicare payment to measurable clinical performance. The second is to integrate Part A and Part B services to facilitate the innovative delivery of health care services and bundled payments methodologies.

Table 3
Title III: Improving the Quality and Efficiency of Health Care

Subtitle A—Transforming The Health Care Delivery System
Part 1—Linking Payment to Quality Outcomes Under the Medicare Program
Part 2—National Strategy to Improve Health Care Quality
Part 3—Encouraging Development of New Patient Care Models
Subtitle B—Improving Medicare for Patients and Providers
Part I—Ensuring Beneficiary Access to Physician Care and Other Services
Part II—Rural Protections
Part III—Improving Payment Accuracy
Subtitle C—Provisions Relating to Part C
Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans
Subtitle E—Ensuring Medicare Sustainability
Subtitle F—Health Care Quality Improvements
Subtitle G—Protecting and Improving Guaranteed Medicare Benefits

Subtitle A of the ACA contains many of the critical reforms in Medicare that are intended to ultimately transform the U.S. health care sector and make it more efficient and effective. If these measures falter and fail, it is hard to envision

151 BD. OF HEALTH CARE SERVS., INST. OF MED., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH (2009).

152 Symposium, *Current Challenges In Comparative Effectiveness Research*, 31 HEALTH AFF., Oct. 2012, at 2160.

substitutes that will be effective in making the Medicare program sustainable over the long term or put the program in a position to evolve into an single payer system.

1. Linking Payment to Quality Outcomes under the Medicare Program (Subtitle A, Part 1)

Subtitle A, Part 1 essentially advances the Medicare value-based purchasing program for hospitals, physicians, and other providers.[153] Table 4 lists the sections in Title III, Subtitle A, Part 1.

Table 4 **Subtitle A—Transforming the Health Care Delivery System** **Part 1—Linking Payment to Quality Outcomes Under the Medicare Program**
Sec. 3001. Hospital Value-Based purchasing program Sec. 3002. Improvements to the physician quality reporting system Sec. 3003. Improvements to the physician feedback program Sec. 3004. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs Sec. 3005. Quality reporting for PPS-exempt cancer hospitals Sec. 3006. Plans for a Value-Based purchasing program for skilled nursing facilities and home health agencies Sec. 3007. Value-based payment modifier under the physician fee schedule Sec. 3008. Payment adjustment for conditions acquired in hospitals

a. Value-Based Purchasing for Hospitals and other Institutional Providers (Sections 3001, 3004-3006)

Section 3001 of the ACA establishes the value-based purchasing program for IPPS hospitals.[154] This program covers 3,500 hospitals in the United States.[155] In spring 2011, CMS issued the final rule establishing the Hospital Value-Based

153 ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o) (Supp. 2011)); *see* CMS, *Medicare Learning Network, Sheet: Hospital Value-Based Purchasing Program*, DHHS, (Nov. 2011), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf; Health Affairs Blog, Health Policy Brief: Pay For Performance (Oct. 11, 2012), *available at* http://healthaffairs.org/blog/2012/10/11/health-policy-brief-pay-for-performance/; *see* Eleanor D. Kinney, The Affordable Care Act and the Medicare Program: Linking Medicare Payment to Quality Performance, 67 New York University Annual Survey of American Law (forthcoming 2013).

154 CMS Issues Final Rule for First Year of Hospital Value-Based Purchasing Program: Final Rule Will Promote Better Clinical Outcomes and Patient Experiences of Care, OFFICE OF PUBLIC AFF., CMS (Apr. 29, 2011), http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3947.

155 *Id.*

Purchasing Program under the Medicare IPPS.[156] The ACA Value-Based Purchasing Program marks a definite departure from how the Medicare program has paid hospitals in the past. CMS asserts:

> Starting in October 2012, Medicare will reward hospitals that provide high quality care for their patients through the new Hospital Value-Based Purchasing Program. This program marks the beginning of an historic change in how Medicare pays health care providers and facilities—for the first time, hospitals across the country will be paid for inpatient acute care services based on care quality, not just the quantity of the services they provide.[157]

The program applies to all Medicare inpatient hospitals' discharges on or after October 1, 2012.[158] The ACA establishes a process for the selection of performance measures and a formula for calculating final payment to hospitals.[159] Funding for value-based incentive payments will come from assigned payment to hospitals under the Medicare prospective payment system.[160] The amount of reduction in FY 2013 is 1.0% and moves to 2.0% by 2017.[161]

Section 3006 of the ACA requires the Secretary to develop a plan to implement a value-based purchasing program for skilled nursing facilities,[162] home health agencies,[163] and ambulatory surgery centers.[164]

The ACA also launches value-based purchasing for other institutional providers. By 2014, Section 3005 of the ACA extends the quality-reporting requirement to long-term care hospitals,[165] inpatient rehabilitation hospitals,[166]

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156 Final Rule, Medicare Program; Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 26,490 (May 6, 2011) (42 C.F.R. Parts 422 and 480); *see also* Proposed Rule, Medicare Program; Hospital Inpatient Value-Based Purchasing Program,76 Fed. Reg. 2454 (Jan. 13, 2011).

157 *Administration Implements New Health Reform Provision to Improve Care Quality, Lower Costs*, HEALTHCARE.GOV (Dec. 22, 2012), http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011a.html.

158 ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(1)(B) (Supp. 2011)).

159 *Id.* § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a) (Supp. 2011); *see* Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: Linking Medicare Payment To Quality Performance*, New York University Annual Survey of American Law (Forthcoming 2013).

160 ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(7)(A) (Supp. 2011)).

161 *Id.* § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(7)(C) (Supp. 2011)).

162 *Id.* § 3006(a).

163 *Id.* § 3006(b).

164 *Id.* § 3006(f).

165 *Id.* § 3004(a) (codified as amended at 42 U.S.C. § 1395ww(m) (Supp. 2011)).

166 *Id.* § 3004 (codified as amended at 42 U.S.C. § 1395ww(j) (Supp. 2011)).

and hospice programs.[167] The Secretary of HHS must develop and publish the quality measures for these institutions by 2012 and make quality data from these institutions available to the public through a website.[168]

Section 3005 of the ACA establishes a quality-reporting program for PPS-Exempt cancer hospitals.[169] Historically, the Medicare program has exempted major cancer hospitals that are designated as comprehensive or clinical cancer centers by the National Institutes of Health from the prospective payment system.[170] Beginning in 2014, cancer hospitals will have to submit data on quality measures to the Secretary in a manner the Secretary specifies.[171] By October 1, 2012, the Secretary must publish quality measures for cancer hospitals that will be effective in fiscal year 2014.[172]

The Medicare program is clearly banking on connecting payment to quality measures to address the cost curve in launching value-based purchasing for hospitals and physicians and moving toward value-based purchasing for other providers. Value-based purchasing is very data driven and depends on generating, collecting, and analyzing large amounts of data from individual providers. Whether the quality measures will be specific and comprehensive enough to generate improvements in care remains a question and has been a consistent concern since CMS has explored value-based payment. It is also possible that the process of collecting data and enforcing payment cuts for failures to meet quality measures will antagonize providers to the point of not participating in the Medicare program.

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167 *Id.* § 3004(c) (codified as amended at 42 U.S.C. § 1395f(i) (Supp. 2011)).

168 *Id.* §§ 3004(a)-(c) (codified as amended at 42 U.S.C. §§ 1395f(i)(5), 1395ww(j)(7) & 1395f(i)(5) (Supp. 2011)); *see* Proposed Rule, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers, 77 Fed. Reg. 27,869 (May 11, 2012); Proposed Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule . . . Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations, 77 Fed. Reg. 44,722 (Jul. 30, 2012) (42 C.F.R pts. 410, 414, 415, 421, 423, 425, 486, and 495).

169 ACA § 3005 (codified as amended at 42 U.S.C. § 1395cc (Supp. 2011)).

170 42 U.S.C. § 1395ww(d)(1)(B)(v); *see* CMS, *Medicare PPS Excluded Cancer Hospitals*, CMS.GOV (May 10, 2013, 3:45 PM), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html.

171 ACA § 3005(2) (codified as amended at 42 U.S.C. § 1395cc(k) (Supp. 2011)).

172 *Id.* § 3005(3) (codified as amended at 42 U.S.C. § 1395cc(k)(W)(3) (Supp. 2011)); *see* NAT'L QUALITY F., PERFORMANCE MEASUREMENT COORDINATION STRATEGY FOR PPS-EXEMPT CANCER HOSPITALS: FINAL REPORT 2 (2012), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CB4QFjAA&url=http%3A%2F%2Fwww.qualityforum.org%2FWorkArea%2Flinkit.aspx%3FLinkIdentifier%3Did%26ItemID%3D71217&ei=mD-UUM_1LaPz0gGG1oDwDg&usg=AFQjCNGwbObNnyy3ND4t5wCY-UZOgF2X1A&sig2=2xCvv0FGM2QhbTTfLRBp8g.pdf.

However, it seems that value-based payment is the only way to ensure that providers provide only necessary, but not excessive, care. The federal government has invested, and continues to invest, enormous funds to develop value-based purchasing and other quality initiatives. Time will tell if the federal government, out of concerns about the federal budget deficit, will continue this investment.

b. Payment Adjustment for Hospital-Acquired Conditions (Section 3008)

An important step toward linking Medicare payment to quality performance was the Medicare program's identification of so-called "never events" and not paying for associated hospital care needed because of the never event.[173] In 2002, NQF published a report, *Serious Reportable Events in Healthcare*, identifying 27 adverse events occurring in hospitals that are "unambiguous, largely preventable, and serious," and that are of concern to both the public and healthcare providers.[174] According to NQF, the report's objective was establishment of "the consensus arrived at by consumers, providers, purchasers, researchers, and other healthcare stakeholders about preventable adverse events, and it expands on the earlier report by including implementation guidance to facilitate consistent reporting."[175]

In the DRA of 2005, Congress required the Secretary to identify conditions that (1) were high cost or high volume or both, (2) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence based guidelines.[176] In August 2007, CMS adopted a final rule identifying eight "never events" for which, beginning Oct. 1, 2008, Medicare would not provide additional payment to hospitals unless the events were present on admission.[177]

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173 *See* CMS, *Medicare Learning Network, Fact Sheet: Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals*, DHHS (Oct. 2012), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/downloads/hacfactsheet.pdf.

174 NAT'L QUALITY F., SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT 5 (2011), *available at* http://www.doh.wa.gov/Portals/1/Documents/2900/NQF2011Update.pdf.

175 *Id.*

176 Deficit Reduction Act (DRA) of 2005, Pub. L. No. 109-171, § 5001(c), 120 Stat. 4 (codified as amended at 42 U.S.C. § 1395ww (2006)); *see* CMS, Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals, DHHS (Oct. 2012), https://www.cms.gov/HospitalAcqCond/downloads/HACFactsheet.pdf.

177 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates, etc., 74 Fed. Reg. 43,754 (Aug, 27, 2009) (42 C.F.R. pts. 412, 413, 415, 485, and 489).

Adverse payment adjustments mark a great change in Medicare's relationship with providers. Formerly, the Medicare program paid providers regardless of whether they generated expenses associated with their errors without question. Now hospitals must bear the cost when they provide highly substandard care. Presumably this will give hospitals a greater incentive to improve safety for their patients.

c. Quality Reporting for Physicians (Sections 3002-3003 & 3007)

The ACA establishes the Physician Feedback/Value-Based Modifier Program, which provides comparative performance information to physicians as part of Medicare's efforts to improve the quality and efficiency of medical care.[178] These goals are achieved, in the words of CMS, "by providing meaningful and actionable information to physicians so they can improve the care they furnish, and by moving toward physician reimbursement that rewards value rather than volume."[179] The Program contains two primary components: (1) the preparation of the Physician Quality and Resource Use Reports (QRURs), and (2) the development and implementation of a Value-Based Payment Modifier (VBPM).[180]

Congress established the Physician Quality Reporting Initiative in the Tax Relief and Health Care Act of 2006.[181] The Physician Quality Reporting Initiative now is a voluntary program for eligible practitioners and provides an incentive payment to physicians and practices that satisfactorily report data on specified quality measures.[182] The ACA extends this voluntary program until 2014.[183]

The ACA expands the current Physician Feedback Reporting initiative.[184] Specifically, the feedback-reporting program uses claims data to provide reports

178 ACA § 3008(b) (codified at 42 U.S.C. § 1395ww (Supp. 2011)).

179 CMS, *supra* note 120; CMS, *Medicare FFS Physician Feedback Program/Value-Based Payment Modifier: Background*, CMS.GOV (May 13, 3:55 PM), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Background.html; American Medical Association, 2012 Physician Quality Reporting System (2012), http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement/clinical-quality/physician-quality-reporting-system-2012.page.

180 *See* CMS, *supra* note 120, at 1.

181 THRCA, Pub. L. No. 109-432, Div. B, § 101(b) 120 Stat. 2922 (codified as amended at 42 U.S.C. § 1395w-4 (2006)).

182 CMS, *Physician Quality Reporting System*, CMS.GOV (May 20, 2013, 4:00 PM), http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index. html?redirect=/PQRS/.

183 ACA § 3002(a) (codified as amended at 42 U.S.C. § 1395w–4(m) (Supp. 2011)).

184 *Id.* § 3003(a)(1) (codified as amended at 42 U.S.C. § 1395w–4(n) (Supp. 2011); *see* Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to

to physicians and physician groups in the QRURs.[185] The QRURs contain information on resource use and the costs and quality of care provided to Medicare patients, including quantification and comparisons of patterns of resource use and costs among physicians and medical practice groups.[186]

For reports on utilization, the Secretary developed an "episode grouper" that combines separate, but clinically related, items and services into an episode of care for an individual patient.[187] The grouper enables production of individualized reports that compare the per capita utilization of physicians to other physicians who see similar patients. The details of the grouper must be made available to the public and endorsed by NQR.[188] Additionally, the methodologies used must meet statutory standards and be available to the public as well.[189] Finally, the feedback program must be coordinated with other value-based purchasing programs.[190] CMS promulgated a proposed rule to implement these and other changes in physician payment in July 2012.[191]

The ACA also consolidated this initiative into the Physician Quality Reporting System (PQRS) and established the *Physician Compare* website.[192] By 2015, eligible professionals must submit data on quality measures for covered professional services or incur a percent reduction in the fee schedule amount for service provided for that pay period.[193] The percentage reductions will be 1.5% in 2015 and 2.0% thereafter.[194] CMS addressed these and other changes in its proposed rule on physician payment in July 2012.[195]

The ACA also contains incentives for physicians to participate in the Maintenance of Certification (MOC) Program operated by the American Board

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Part B for CY 2011, 75 Fed. Reg. 73,169 (Nov. 29, 2010) (42 C.F.R. pts. 405, 409, 410, 411, 413, 414, 415, and 424).

185 CMS, *Medicare FFS Physician Feedback Program/Value-Based Payment Modifier,* CMS.GOV (May 20, 2013: 4:10PM), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html?redirect=/physicianfeedbackprogram.

186 *Id.*

187 ACA § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w–4(n)(9)(A) (i),(ii) (Supp. 2011)).

188 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w–4(n)(A)(9) (iii),(iv) (Supp. 2011)).

189 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. §§ 1395w–4(n)(9)(A) (C),(F) (Supp. 2011)).

190 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w–4(n)(10) (Supp. 2011)).

191 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates, etc., 74 Fed. Reg. 43,754 (Aug, 27, 2009) (42 C.F.R. pts. 412, 413, 415, 485, and 489).

192 *Id.*

193 ACA § 3002(b) (codified as amended at 42 U.S.C. § 1395w–4(a)(8)(A) (Supp. 2011)).

194 *Id.*

195 *See,* Medicare Program, 74 Fed. Reg. 43, 754.

of Medical Specialties.[196] This program requires physicians with medical specialty certifications to participate in continuing medical education and other activities to maintain current in their specialty.[197] The ACA provides that physicians who are eligible for the PQRS can receive an additional 0.5% incentive payment if they meet the MOC requirements as well.[198]

The ACA section 3007 mandates that, by 2015, the Secretary must establish the VBPM that provides for differential payment to physicians or physicians groups based on quality performance.[199] To establish the VBPM, the Secretary must develop appropriate risk adjusted measures of quality of care, which also reflects outcomes of care. ACA requires that implementation begin with rulemaking for Fiscal Year 2013.[200]

Beginning January 1, 2015, CMS must apply the VBPM to specific physicians and physician groups that CMS determines appropriate. By no later than January 1, 2017, the VBPM must be applied to all physicians and physician groups.[201] In applying the payment modifier, the Secretary must take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities.[202]

Quality reporting and value-based purchasing for physicians should hopefully impose the same incentives on physicians for quality of care over volume of care as a way to maximize payment. However, quality reporting and value-based purchasing pose special problems for physicians. Quality reporting and value-based purchasing are data-intensive enterprises. Thus, to participate in these initiatives, physicians and their practices will need to submit large quantities of patient data to participate in this program. Such requirements could have an impact on patient care, as physicians often enter data on patients as they provide care. Such an enterprise, to say the least, could be distracting from the important physician-patient encounters, which are so necessary for high-quality care.

196 AM. BD. MED. SPECIALTIES, *About ABMS Maintenance of Certification*, (2012) http://www.abms.org/maintenance_of_certification/.

197 *Id.*

198 ACA § 3002(c) as amended by § 10327(b) (codified as amended at 42 U.S.C. § 1395w–4(k)(4) (Supp. 2011)).

199 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w–4(p)(2) (Supp. 2011)).

200 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w–4(p)(4) (Supp. 2011)).

201 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w–4(p)(4) (Supp. 2011)).

202 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w–4(p)(6) (Supp. 2011)).

2. Developing a National Strategy to Improve Health Care Quality (Subtitle A, Part 2)

Subtitle A, Part 2, calls for the development of a National Strategy to Improve Health Care Quality.[203] To develop this strategy, the Secretary of HHS is to convene an interagency working group on health care quality that will focus primarily on developing quality measures and methods for measuring quality.[204] HHS has initiated the development of a national strategy as directed.[205] In the first mandated report to Congress, CMS established 3 aims and 6 priorities, which are displayed in Table 5.[206] HHS presented a second report to Congress on progress with this initiative in April 2012.[207]

The first mandated report also required CMS to report on a process of developing a universal quality strategy that will reconcile and harmonize the development of quality performance measures and other standards of the various public and private organizations involved in the development of these measures and standards. In its second 2012 report to Congress on this strategy, CMS stated:

> One of the primary objectives of the National Quality Strategy is to build a national consensus on how to measure quality so that stakeholders can align their efforts for maximum results. The strategy itself serves as a framework for quality measurement, measure development, and analysis of where everyone can do more, including across HHS agencies and programs as well as in the private sector. This alignment of measurement creates shared accountability across health systems and stakeholders around the country for improving patient-centered outcomes.[208]

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203 *Id.* § 3011.

204 *Id.* §§ 3012-3014.

205 National Quality Strategy Will Promote Better Health, Quality Care for Americans, HHS.GOV, (Mar. 21, 2011), http://www.hhs.gov/news/press/2011pres/03/20110321a.html.

206 CMS, REPORT TO CONGRESS: NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE (2011), *available at* http://www.healthcare.gov/law/resources/reports/quality 03212011a.html.

207 CMS, 2012 ANNUAL REPORT TO CONGRESS: NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE, DHHS 1 (2012), *available at* http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf.

208 *Id.* at 2.

Table 5
National Quality Strategy Aims and Priorities

National Quality Strategy's three aims:
1. Better Care: Improve the overall quality of care, by making health care more patient-centered, reliable, accessible, and safe
2. Healthy People/Healthy Communities: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care
3. Affordable Care: Reduce the cost of quality health care for individuals, families, employers, and government

National Quality Strategy's six priorities:
1. Making care safer by reducing harm caused in the delivery of care
2. Ensuring that each person and family are engaged as partners in their care
3. Promoting effective communication and coordination of care
4. Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
5. Working with communities to promote wide use of best practices to enable healthy living.
6. Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models

The successful development and implementation of the National Quality Strategy is important and will greatly facilitate other approaches to improve quality and efficiency throughout the ACA. So far, it seems that this effort to develop a National Quality Strategy has been relatively well received among stakeholders, which is an important indicator of success.[209]

3. Developing New Patient Care Models (Subtitle A, Part 3)

Subtitle A, Part 3, Encouraging Development of New Patient Care Models, includes other strategies to control Medicare expenditures.[210] Table 6 lists the authorities for these new patient care models. These models are designed to make the delivery of, and payment for, health care services to Medicare fee-for-service beneficiaries more integrated and efficient and therefore, less costly. Subtitle A, Part 3, contains most of the innovative programs to reform the way in which medical care is delivered, particularly for those with chronic disease.

209 *See, e.g.*, David Nash, *National Quality Strategy: Right Idea at the Right Time*, MEDPAGE TODAY (May 11, 2013, 5:00PM), http://www.medpagetoday.com/Columns/FocusonPolicy/23303, NORTHEAST BUSINESS GROUP ON HEALTH, *HHS Releases National Quality Strategy that Aims to Promote Better Health, Quality Care* (2011), http://nebgh.org/blog/?p=95.

210 ACA §§ 3021-3027.

Table 6 Subtitle A—Transforming The Health Care Delivery System Part 3—Encouraging Development of New Patient Care Models
Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS Sec. 3022. Medicare shared savings program Sec. 3023. National pilot program on payment bundling Sec. 3024. Independence at home demonstration program Sec. 3025. Hospital readmissions reduction program Sec. 3026. Community-Based Care Transitions Program Sec. 3027. Extension of gainsharing demonstration

a. Center for Medicare and Medicaid Innovation (CMI) (Section 3021)

Section 3021 of the ACA calls for the creation of the Center for Medicare and Medicaid Innovation (CMI).[211] The purpose of CMI is "to test innovative payment and service delivery models to reduce program expenditures" and "improve the coordination, quality, and efficiency of health care services."[212] CMI has been quite active in launching new and continuing old initiatives.[213] Currently, it is engaged in research and analysis on the following Medicare issues: accountable care organization demonstrations, bundled payment demonstrations, and the independence at home demonstration, among other projects.[214]

b. Medicare Shared Savings Program (Section 3022)

A very important strategy that compliments value-based purchasing is the Medicare shared savings program in Section 3022 of the ACA.[215] This shared savings program is intended to facilitate coordination and cooperation among

211 *Id.* § 3021(a) (codified as amended at 42 U.S.C. § 1315a (Supp. 2011)).

212 *See* Stuart Guterman et al., *Innovation in Medicare and Medicaid will be Central to Health Reform's Success*, 29 HEALTH AFF. 1188, 1188-92 (2010); Meredith B. Rosenthal, *Hard Choices—Alternatives for Reining in Medicare and Medicaid Spending*, NEW ENG. J. MED. 364, 1887-88 (2011).

213 CMS, *One Year of Innovation: Taking Action to Improve Care and Reduce Costs*, DHHS (Jan. 2012), http://www.innovations.cms.gov/Files/reports/Innovation-Center-Year-One-Summary-document.pdf.

214 CMS, *Welcome to the CMS Innovation Center*, CMS.GOV (May 1, 2013, 5:50 PM), http://www.innovations.cms.gov/.

215 ACA § 3022 (codified at 42 U.S.C. § 1395(jjj) (Supp. 2011)); Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67, 802 (Nov. 2, 2011) (42 C.F.R. pt. 425); *see* Paul B. Ginsburg, *Spending to Save—ACOs and the Medicare Shared Savings Program*, 365 NEW ENG. J. MED. 2085, 2085-86 (2011).

providers to improve the quality of care for fee-for-service Medicare beneficiaries. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO).[216]

CMS defines ACOs as "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients."[217] The goal of coordinated care is "to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors."[218] Under the program, groups of providers of services and suppliers can work together to manage and coordinate care in an ACO, and, if they meet quality performance standards, they may receive payments for shared savings.[219]

CMS has initiated a demonstration to test two models of ACOs: the Pioneer ACO Model and the Advance Payment ACO Model.[220] The Pioneer ACO Model was designed specifically for organizations with "experience offering coordinated, patient-centered care, and operating in ACO-like arrangements."[221] There are thirty-two organizations participating in the Pioneer ACO Model. The Advanced Payment ACO Model provides additional support to physician-owned and rural providers who would benefit from additional start-up resources to build the necessary infrastructure, such as new staff or information technology systems.[222]

The number of providers who have launched ACOs is impressive. According to CMS, as of January 2013, there were 106 ACOs, saving up to $940 million over four years.[223] Roughly half of ACOs are physician-led organizations that serve fewer than 10,000 beneficiaries and about 20 percent of ACOs include community health centers, rural health clinics, and critical access hospitals that serve low-income and rural communities.[224]

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216 CMS, *Shared Savings Program*, CMS.GOV (Apr. 30, 2013, 11:56 PM), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/.

217 CMS, Accountable Care Organizations, CMS.GOV (Mar. 22, 2013, 5:38 AM), http://innovation.cms.gov/initiatives/aco/.

218 *Id.*

219 ACA § 3023 (codified as amended at 45 U.S.C. § 1395cc–4 (Supp. 2011)).

220 CMS, *Pioneer Accountable Care Organization Model: General Fact Sheet*, DHHS (Sept. 2012), http://innovations.cms.gov/Files/fact-sheet/Pioneer-ACO-General-Fact-Sheet.pdf.

221 *Id.*

222 *Id.*

223 More Doctors, Hospitals Partner to Coordinate Care for People with Medicare Providers Form 106 New Accountable Care Organizations, HHS.GOV, http://www.cms.gov/apps/media/press/release.asp?Counter=4501&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

224 *Id.*

Although the provider community was initially skeptical of ACOs,[225] as the numbers indicate, they have responded to the initiative relatively enthusiastically. Donald Berwick, the former CMS administrator, has indicated that CMS made many changes in the final rules for ACOs to accommodate provider comments and facilitate provider participation.[226] Empirical research suggests that, while there is much to be done, ACOs are very promising with respect to meeting their goals.[227] Even *Forbes Magazine* lauds the performance of ACOs.[228] An interesting report from an industry study is remarkably positive about ACOs and their accomplishments to date:

> For many of us in the healthcare industry, the real potential game-changer in the Affordable Care Act was not the highly publicized provisions—the creation of insurance exchanges or its embrace of guaranteed issue, community rating, and regulated medical loss ratios. Rather, it was the way ACA opened the door to accountable care organizations (ACOs) in Medicare. Here at last was a development in US healthcare that would shift the focus to delivery and encourage provider organizations to compete on quality and price—something the traditional fee-for-service system has failed at rather spectacularly. We believed—and still do—that as this sort of competition is successfully introduced into the US system, it will inevitably spread, enabling and accelerating a movement toward healthcare that is priced and paid for in terms of value, not volume of services rendered.[229]

225 Elliott S. Fisher & Stephen M. Shortell, *Accountable Care Organizations Accountable for What, to Whom, and How*, 304 JAMA 1715, 1715-16 (2010).

226 Donald M. Berwick, *Making Good on ACOs' Promise—The Final Rule for the Medicare Shared Savings Program*, 365 NEW ENG. J. MED. 1753, 1754 (2011).

227 Elliott S. Fisher et al., *A Framework For Evaluating The Formation, Implementation, And Performance Of Accountable Care Organizations*, 31 HEALTH AFF. 2368, 2368-69 (2012); Bridget K. Larson et al., *Insights From Transformations Under Way At Four Brookings-Dartmouth Accountable Care Organization Pilot Sites*, 31 HEALTH AFF. 2395, 2395 (2012).

228 Bruce Japsen, *Obamacare's Accountable Care Approach Reaches 1 in 10 In U.S.*, FORBES (Nov. 26, 2012, 9:00 AM), http://www.forbes.com/sites/brucejapsen/2012/11/26/obamacares-accountable-care-approach-reaches-1-in-10-in-u-s/.

229 NIYUM GANDHI & RICHARD WEIL, THE ACO SURPRISE (2012), *available at* http://www.oliverwyman.com/media/OW_ENG_HLS_PUBL_The_ACO_Surprise.pdf.

c. Other Reforms to Improve Efficiency of Care (Sections 3023-3027)

There are several initiatives in the ACA that seek to make payment methodologies encouraging providers to make efficiencies. A major payment reform in this regard is the shared savings program with ACOs discussed above.

The ACA section 3027 extends the "gainsharing demonstration" established under the DRA of 2005.[230] The basic theory of this demonstration is that providing payments to physicians that "represent solely a share of the savings incurred as a result of collaborative efforts" will "improve overall quality and efficiency."[231] This demonstration examines whether the practice of "gainsharing" is an effective means of aligning financial incentives to enhance quality and efficiency of care.[232]

The ACA section 3023 also calls for a national pilot program on payment bundling.[233] The pilot program explores ways to pay groups of providers for services associated with an episode of care and move away from the practice of essentially paying the bills of lots of individual providers. The basic idea is that such bundling encourages providers to work together in efficient ways to care for the patient in a cost effective manner and not seek to maximize their individual reimbursements. In this program, CMS will pay a subset of Medicare providers a single payment for an episode of acute care in a hospital, followed by post acute care in a skilled nursing or rehabilitation facility, the patient's home, or other appropriate setting.[234]

The ACA section 3026 establishes a Community-Based Care Transitions Program under which CMS will fund entities that furnish improved care transition services to high-risk Medicare beneficiaries without reducing quality.[235] The idea is that various entities, typically hospitals and community-

230 ACA § 3027 (codified at § 5007 of the DFA).

231 CMS, *Medicare Hospital Gainsharing Demonstration,* CMS.GOV (2006), http://www.cms.gov/DemoProjectsEvalRpts/downloads/DRA5007_Fact_Sheet.pdf.

232 CMS.gov, Demonstrations, Details for DRA 5007 (2011), http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1186805.html.

233 ACA § 3024 (codified at 42 U.S.C. § 1395cc–5 (Supp. 2011)); *see* Neeraj Sood et al., *Medicare's Bundled Payment Pilot for Acute and Postacute Care: Analysis and Recommendations on Where To Begin*, 30 HEALTH AFF. 1708, 1708-09 (2011).

234 Neeraj Sood et al., *Medicare's Bundled Payment Pilot for Acute and Postacute Care: Analysis and Recommendations on Where To Begin*, 30 HEALTH AFF. 1708, 1708-09 (2011).

235 ACA § 3026; *see* CMS, Community-Based Care Transitions Program, CMS.GOV (2012), http://www.innovations.cms.gov/initiatives/Partnership-for-Patients/CCTP/index.html?itemID=CMS1239313; Chris Fleming, *Health Policy Brief: Improving Transitions*, HEALTH AFF. BLOG (Sept. 21, 2012), http://healthaffairs.org/blog/2012/09/21/health-policy-brief-improving-care-transitions/; Eric A. Coleman et al., *The Care Transitions Intervention: Results of a Randomized Controlled Trial*, 166 ARCHIVES INTERNAL MED. 1822 (2006).

based organizations, will formally collaborate and provide transition services for high-risk Medicare beneficiaries to ensure timely post-discharge follow-up services.[236] The partnership would submit a proposal on how it would deliver these transition services.[237]

Section 3024 of the ACA establishes the "Independence at Home Demonstration program."[238] This program will test payment incentives and service delivery models for the care of chronically ill patients that utilize physician and nurse practitioner directed home-based primary care teams.

Many of the initiatives in Subtitle A, Part 3 endeavor to bundle payments, change incentives, and move toward better coordinated care. However, these initiatives must be executed with care to be sure that providers use of the bundled payment for patient care and, more importantly, not avoid taking care of sicker and more difficult patients.[239] And it is also important to maintain funding levels to make success possible. The success of these reforms would put the Medicare program in a better position to evolve into a sustainable single payer system.

The ACA section 3025 establishes authority for reducing payment for readmissions to hospitals.[240] Readmissions to hospitals have been a difficult and costly problem for the Medicare program since the implementation of the Medicare prospective payment system in the early 1980s.[241] The problem reflects deficiencies in discharge planning for patients with multiple chronic conditions or poor support systems at home. In 2005, MEDPAC reported that in 2005, 17.6% of hospital admissions resulted in readmissions within thirty days of discharge, 11.3% within fifteen days, and 6.2% within seven days.[242] Other research reported similar findings.[243] Through demonstrations and other analysis, CMS has been working on how to tailor Medicare payment rates for hospital

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236 ACA § 3026(a)(2); *see Independence at Home Demonstration*, (2012), http://www.innovations.cms.gov/Files/fact-sheet/IAHfactsheet.pdf.

237 *Id.* § 3026(a)(2).

238 *Id.* § 3024 (codified at 42 U.S.C. § 1395cc–5 (Supp. 2011)).

239 Meredith B. Rosenthal, *Hard choices—Alternatives for Reining in Medicare and Medicaid Spending*, 364 NEW ENG. J. MED. 1887, 1887 (2011).

240 ACA § 3025 (codified at 42 U.S.C. § 1395www (Supp. 2011)); *see* JULIE STONE & GEOFFREY J. HOFFMAN, MEDICARE HOSPITAL READMISSIONS: ISSUES, POLICY OPTIONS AND PPACA, *available at* http://www.hospitalmedicine.org/AM/pdf/advocacy/CRS_Readmissions_Report.pdf.

241 Gerard F. Anderson & Earl P. Steinberg, *Hospital Readmissions in the Medicare Population*, 311 NEW ENG. J. MED. 1349, 1349-52 (1984).

242 *Report to Congress: Promoting Greater Efficiency in Medicare*, MEDPAC (Jun. 2007), www.medpac.gov/documents/Jun07_EntireReport.pdf; JULIE STONE & GEOFFREY J. HOFFMAN, MEDICARE HOSPITAL READMISSIONS: ISSUES, POLICY OPTIONS AND PPACA (2010), *available at* http://www.hospitalmedicine.org/AM/pdf/advocacy/CRS_Readmissions_Report.pdf.

243 Stephen F. Jencks et al., *Rehospitalizations Among Patients in the Medicare Fee-for-Service Program*, 360 NEW ENG. J. MED. 1418 (2009); *see also* JENNY MINOT, REDUCING HOSPITAL READMISSIONS 2 (2008), *available at* http://www.academyhealth.org/files/publications/Reducing_Hospital_Readmissions.pdf.

readmissions.[244] The ACA established the Hospital Readmissions Reduction Program, effective October 1, 2012.[245] Under this program, payments for certain readmissions of eligible hospitals are reduced in order to account for excess readmissions.[246] CMS has promulgated regulations to implement the Hospitals Readmissions Reduction Program.[247]

The initiative to reduce readmissions to hospitals is a critical reform. Implementation of the program has been controversial with 2,217 hospitals sustaining penalties in the program's first year.[248] While quite controversial among hospitals, there are indications that hospitals are taking steps to address the readmissions problem with serious effort.[249] This initiative is persuasive conformation that payment methodologies can influence provider behavior.

B. Improving Medicare for Patients and Providers (Title III, Subtitle B)

Subtitle B contains an assortment of provisions directed at improving various Medicare program policies. The changes are contained in three parts: (1) Ensuring Beneficiary Access to Physician Care and Other services, (2) Rural Protections, and (3) Improving Payment Accuracy. Table 7 displays the statutory sections in Subtitle B, Part I.

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244 *See* Richard F. Averill et al., *Redesigning the Medicare Inpatient PPS to Reduce Payments to Hospitals with High Readmission Rates*, 30 HEALTH CARE FIN. REV. 1 (2009).

245 ACA § 3025 (codified at 42 U.S.C. § 1395ww(q) (Supp. 2011), as amended by ACA §§ 3001, 3008); *see* CMS, *Community-based Care Transitions Program*, CMS.GOV (2012), http://www.innovations.cms.gov/initiatives/Partnership-for-Patients/CCTP/index.html? itemid=cms1239313.

246 ACA § 3025 (codified at 42 U.S.C. § 1395ww(q)(q) (Supp. 2011), as amended by ACA §§ 3001, 3008); *see* CMS, *Hospital Readmissions Reduction Program*, CMS.GOV (2012), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html.

247 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, 76 Fed. Reg. 51,476 (Aug. 18, 2011) (42 C.F.R. pts. 412, 413 and 476).

248 Jordan Rau, *Medicare Revises Hospitals' Readmissions Penalties*, KAISER HEALTH NEWS (Oct. 2, 2012), http://www.kaiserhealthnews.org/Stories/2012/October/03/medicare-revises-hospitals-readmissions-penalties.aspx.

249 Douglas McCarthy et al., *Recasting Readmissions by Placing the Hospital Role in Community Context*, 309 JAMA 351 (2013); Amy Boutwell, *Time To Get Serious About Hospital Readmissions*, HEALTH AFF. BLOG (Oct. 10, 2012), http://healthaffairs.org/blog/2012/10/10/time-to-get-serious-about-hospital-readmissions/.

Table 7 Subtitle B—Improving Medicare for Patients and Providers Part I—Ensuring Beneficiary Access to Physician Care and Other Services
Sec. 3101. Increase in the physician payment update (repealed) Sec. 3102. Extension of the work geographic index floor and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule Sec. 3103. Extension of exceptions process for Medicare therapy caps Sec. 3104. Extension of payment for technical component of certain physician pathology services Sec. 3105. Extension of ambulance add-ons Sec. 3106. Extension of certain payment rules for long-term care hospital services and of moratorium on the establishment of certain hospitals and facilities Sec. 3107. Extension of physician fee schedule mental health add-on Sec. 3108. Permitting physician assistants to order post-Hospital extended care services Sec. 3109. Exemption of certain pharmacies from accreditation requirements Sec. 3110. Part B special enrollment period for disabled TRICARE beneficiaries Sec. 3111. Payment for bone density tests Sec. 3112. Revision to the Medicare Improvement Fund Sec. 3113. Treatment of certain complex diagnostic laboratory tests Sec. 3114. Improved access for certified nurse-midwife services

1. Ensuring Beneficiary Access to Physician Care and Other Services (Subtitle B, Part I).

This part contains fourteen sections with provisions modifying physician payment methodologies under Part B of the Medicare Program. Perhaps the most important change is the extension of the work geographic index floor[250] and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule.[251] A geographic practice cost index (GPCI) has been established for every Medicare payment locality for each of the three components of a procedure's relative value unit (i.e., the RVUs for work, practice expense, and malpractice).[252] The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.

250 ACA § 3102(a) (codified as amended at 42 U.S.C. § 1395w–4(e)(1)(E) (Supp. 2011)).

251 *Id.* § 3102(b) (codified as amended at 42 U.S.C. § 1395w4(e)(1) (Supp. 2011)).

252 CMS, Overview. CMS.GOV (Mar. 18, 2013), https://www.cms.gov/apps/physician-fee-schedule/overview.aspx; *see* THOMAS MACURDY ET AL., REVISIONS TO THE SIXTH UPDATE OF THE GEOGRAPHIC PRACTICE COST INDEX: FINAL REPORT (2011), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2012_Revisions_to_the_6th_GPCI_Update-Final_Report.pdf.

The ACA originally had a provision to perform the so-called "doc fix" and finally readjust the impact of the SGR. [253] Because of political controversy, this provision was repealed in the Health Care and Education Reconciliation Act of 2010.[254] The American Taxpayer Relief Act of 2012 (ATRA) recently enacted to address the so-called "fiscal cliff," postponed implementation of the statutory reduction of Medicare payments to physicians of approximately 26.5% as required under the SGR for another few years.[255]

2. Rural Protections (Subtitle B, Part II).

Part II, displayed in Table 8, contains seven sections that address problems of rural providers, particularly hospitals.[256] Rural hospitals today and historically have experienced unique problems with respect to Medicare payment because of their comparably smaller sizes and more limited assets.[257] Rural hospitals experience "Medicare payment challenges" due to workforce shortages, rising health care liability premiums and poor access to capital.[258] Part II also contains a host of different payment policies to assist rural hospitals in maintaining financial sustainability.

These measures appear to be proceeding with relatively little controversy. They are essentially modifications and continuations of existing programs that are generally quite popular with providers.

3. Improving Payment Accuracy (Subtitle B, Part III).

Part III, as displayed in Table 8, contains provisions for improving payment accuracy through the reform of payment methods for home health care,[259] hospice services,[260] medical imaging,[261] electronic wheelchairs,[262] among many other items and services. The ACA also updates Disproportionate Share (DSH) payments to hospitals that serve large numbers of Medicare, Medicaid and

253 ACA § 3101.

254 Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (codified as amended in scattered sections of the U.S.C.).

255 American Tax Payer Relief Act of 2012, Pub. L. No. 112-240, 126 Stat. 2313 (codified as amended in scattered sections of the U.S.C.).

256 ACA §§ 3121-3129.

257 Am. Hosp. Ass'n, *Rural Health Care* (Apr. 15, 2013), http://www.aha.org/advocacy-issues/rural/index.shtml.

258 *Id.*

259 ACA § 3131.

260 *Id.* § 3132.

261 *Id.* § 3135.

262 *Id.* § 3136.

uninsured patients.[263] Specifically, section 3133 modifies Medicare DSH payments to reflect lower uncompensated care costs associated with decreases in the number of uninsured.[264]

Table 8 **Subtitle B—Improving Medicare for Patients and Providers** **Part II—Rural Protections**
PART II—RURAL PROTECTIONS Sec. 3121. Extension of outpatient hold harmless provision Sec. 3122. Extension of Medicare reasonable costs payments for certain clinical diagnostic laboratory tests furnished to hospital patients in certain rural areas Sec. 3123. Extension of the Rural Community Hospital Demonstration Program Sec. 3124. Extension of the Medicare-dependent hospital (MDH) program Sec. 3125. Temporary improvements to the Medicare inpatient hospital payment adjustment for low-volume hospitals Sec. 3126. Improvements to the demonstration project on community health integration models in certain rural counties Sec. 3127. MedPAC study on adequacy of Medicare payments for health care providers serving in rural areas Sec. 3128. Technical correction related to critical access hospital services Sec. 3129. Extension of and revisions to Medicare rural hospital flexibility Program

The ACA modification of Medicare DSH payments may have to be changed in light of the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*.[265] In this decision, the Supreme Court ruled that the federal government could not terminate all federal matching funds for state Medicaid programs if states declined to implement the Medicaid expansion in Title II of the ACA.[266] The ACA provisions reducing Medicare DSH payments are predicated on the expectation that states would have to adopt the ACA Medicaid expansions. Of note, the ARRA actually rebased state disproportionate share hospital payments achieving substantial savings.[267]

263 *Id.* § 3133, as amended by HCERA § 1104 (codified as amended at 2 U.S.C. § 1395ww(r) (Supp. 2011)); CMS, *Disproportionate Share Payments: Rural Hospital Fact Sheet Series*, DHHS (Jan. 2013), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Disproportionate_Share_Hospital.pdf.

264 ACA § 3133, as amended by HCERA § 1104 (codified as amended at 2 U.S.C. § 1395ww(r) (Supp. 2011)); *see* Irwin Redlener & Roy Grant, *America's Safety Net and Health Care Reform—What Lies Ahead?* 361 NEW ENG. J. MED. 2201 (2009).

265 132 S. Ct. 2566, 2591-93 (2012).

266 ACA, Title II.

267 ARRA § 641 (codified as amended at 42 U.S.C. § 1396r–4(f)(8) (Supp. 2011)).

C. Provisions Relating to Part C (Title III, Subtitle C)

The ACA also made substantial changes to Medicare Part C (the Medicare Advantage (MA) program), which are presented in Table 9. The ACA will reduce payments to MA plans over time to bring Part C expenditures in line with fee-for-service Medicare.[268] Since the MMA of 2003, the Medicare program has paid higher rates for beneficiaries enrolled in MA plans then for beneficiaries in fee-for service Medicare.[269] In 2010, MEDPAC reported that the Medicare program spent roughly $14 billion more for beneficiaries enrolled in MA plans than for beneficiaries in the Medicare Fee-for Service program.[270] Under the ACA, Medicare payments to plans will be predicated on the average of the bids submitted by plans in each market.[271] New payments will be implemented over a four-year transition period.[272]

The ACA imposed significant cuts in payments to MA plans that have proven difficult to implement. The ACA required that, effective January 1, 2012, CMS must provide quality bonus payments to MA plans based on a 5-star quality rating system it developed.[273] Instead, in November 2010, CMS announced that it would waive the ACA 5-star quality rating system provisions and that it would determine quality bonus payments for 2012 through 2014 under the massive Medicare Advantage Quality Bonus Payment Demonstration.[274] There is considerable political debate over the advisability of CMS' decision given the cost and scope of the demonstration.[275] The U.S. GAO took the position that

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268 ACA § 3201 as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w–23 (Supp. 2011)).

269 Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C and 26 U.S.C.).

270 *Report to Congress: Medicare Payment Policy,* MEDPAC (Mar. 2010), http://medpac.gov/documents/Mar10_EntireReport.pdf.

271 ACA § 3201(a) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w–23 (Supp. 2011)).

272 *Id.* § 3201(b) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. §1395w–23 (Supp. 2011)).

273 *Id.* § 3201(c) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w–23 (Supp. 2011)).

274 *Health Policy Briefs: Medicare Advantage Plans*, HEALTH AFF. (Jun. 15, 2011), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=48; *Medicare Advantage Plan Star Ratings and Bonus Payments in 2012*, KAISER FAM. FOUND. (Nov. 1, 2011), http://www.kff.org/medicare/upload/8257.pdf.

275 *See GAO Report, The Obama Administration's $8 Billion Extralegal Healthcare Spending Project*, COMM. OVERSIGHT & GOV'T. REFORM (Jul. 25, 2012, 9:30 AM), http://oversight.house.gov/hearing/gao-report-the-obama-administrations-8-billion-extralegal-healthcare-spending-project/.

HHS exceeded its authority in launching this demonstration rather than implementing the ACA.[276]

Table 9 Subtitle C—Provisions Relating to Part C
Sec. 3201. Medicare Advantage payment Sec. 3202. Benefit protection and simplification Sec. 3203. Application of coding intensity adjustment during MA payment transition Sec. 3204. Simplification of annual beneficiary election periods Sec. 3205. Extension for specialized MA plans for special needs individuals Sec. 3206. Extension of reasonable cost contracts Sec. 3207. Technical correction to MA private fee-for-service plans Sec. 3208. Making senior housing facility demonstration permanent Sec. 3209. Authority to deny plan bids Sec. 3210. Development of new standards for certain Medigap plans

D. Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans (Title III, Subtitle D)

Perhaps the largest Medicare expansion in the ACA is closing the so-called "donut hole" coverage gap in the Medicare prescription drug benefit. The ACA started the process of closing the donut hole by providing a rebate for beneficiaries who had reached the gap in coverage in 2010.[277] Also as a condition of having their drugs included in the Part D program, pharmaceutical manufacturers must provide a fifty percent discount to Part D beneficiaries for brand name pharmaceuticals during the coverage gap.[278] As is evident from Table 10, many provisions in Subtitle D are intended to reduce the cost of coverage to lower income Medicare beneficiaries and reduce subsidies for higher income beneficiaries. Other important changes include improvements in the appeal procedures associated with Part D benefits.[279]

While the ACA closes the "donut hole" in the Medicare prescription drug benefit, neither the ACA nor subsequent legislation has authorized the federal

276 Letter from Lynn H. Gibson, General Counsel of the US Government Accounting Office to the Honorable Kathleen Sebelius, Secretary of Health and Human Services regarding Medicare Advantage Quality Bonus Payment Demonstration (July 11, 2012), http://www.gao.gov/assets/60.0/592303.pdf.

277 ACA § 3315 as amended by HCERA § 1101(a) (codified at 42 U.S.C. § 1395w–152 (Supp. 2011)).

278 *Id.* § 3301(b) as amended by HCERA § 1101(b)(2)(A) (codified as amended at 42 U.S.C. § 1395w–114a (Supp. 2011)).

279 *Id.* §§ 3311-3312 (codified as amended at 42 U.S.C. §§ 1395w–154, 1395w–104(b)(3)(H) (Supp. 2011)).

government to negotiate prices with pharmaceutical manufacturers. This block on negotiating prices is costing the government millions of dollars.[280] Another issue is how Congress will fully implement the plan of closing the donut hole by 2020. It seems likely that this expansion will be the target of budget cutters as such cuts would not take away benefits but just postpone new benefits.

Table 10 **Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans**
Sec. 3301. Medicare coverage gap discount program Sec. 3302. Improvement in determination of Medicare part D low-income benchmark premium Sec. 3303. Voluntary de minimis policy for subsidy eligible individuals under prescription drug plans and MA–PD plans Sec. 3304. Special rule for widows and widowers regarding eligibility for low-income assistance Sec. 3305. Improved information for subsidy eligible individuals reassigned to prescription drug plans and MA–PD plans Sec. 3306. Funding outreach and assistance for low-income programs Sec. 3307. Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs Sec. 3308. Reducing part D premium subsidy for high-income beneficiaries Sec. 3309. Elimination of cost sharing for certain dual eligible individuals Sec. 3310. Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA–PD plans Sec. 3311. Improved Medicare prescription drug plan and MA–PD plan complaint system Sec. 3312. Uniform exceptions and appeals process for prescription drug plans and MA–PD plans Sec. 3313. Office of the Inspector General studies and reports Sec. 3314. Including costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D Sec. 3315. Immediate reduction in coverage gap in 2010

E. Ensuring Medicare Sustainability (Title III, Subtitle E)

Subtitle E, Ensuring Medicare Sustainability, is one of the more controversial provisions of the ACA. The first two provisions of Subtitle E are relatively straightforward. Section 3401 adds a productivity adjustment to the market basket update for inpatient hospitals, home health providers, nursing homes,

280 Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D Of Medicare? And If So, How?* 27 HEALTH AFF. 33, 33-35 (2008).

hospice providers, inpatient psychiatric facilities, long-term care hospitals, and inpatient rehabilitation facilities.[281] Section 3402 provides a temporary adjustment to the calculation of Part B premiums.[282]

Table 11 **Subtitle E—Ensuring Medicare Sustainability**
Sec. 3401. Revision of certain market basket updates and incorporation of productivity improvements into market basket updates that do not already incorporate such improvements Sec. 3402. Temporary adjustment to the calculation of part B premiums Sec. 3403. Independent Payment Advisory Board

The controversial provision is the establishment of the Independent Payment Advisory Board (IPAB), which is intended to reduce the per capita rate of growth in Medicare spending.[283] The IPAB is a 15-member panel charged with recommending a set of Medicare program changes if program spending growth exceeds specified targets in 2015.[284] Section 3403 establishes a complicated procedure by which the Chief Actuary of CMS annually determines the projected per capita growth rate of Medicare beneficiaries for that year and the next year.[285] If the projection for the second year exceeds the target growth rate for that year, the board is required to develop and submit a proposal containing recommendations to reduce the Medicare per capita growth rate as directed by statute.[286] The Secretary must implement such proposals, unless Congress enacts legislation pursuant to this section.

The IPAB is one of the most politically controversial reforms in the ACA.[287] It is so politically controversial that President Obama has yet to nominate the board's members as the Senate Republicans are likely to hold up confirmation. The AMA is bitterly opposed to the Board, stating, "The AMA continues to fight

281 ACA § 3401.

282 *Id.* § 3402 (codified as amended at 42 U.S.C. § 1395r(i) (Supp. 2011)).

283 *Id.* § 3403(a) (codified as amended at 42 U.S.C. § 1395kkk(b) (Supp. 2011)).

284 *A Primer on Medicare Financing*, KAISER FAM. FOUND. (Jan 31, 2011), http://kff.org/health-reform/issue-brief/a-primer-on-medicare-financing/.

285 ACA § 3202(a) (codified as amended at 42 U.S.C. § 1395kkk(v)(b)(1) (Supp. 2011)).

286 *Id.* § 3202(a) (codified as amended at 42 U.S.C. § 1395kkk(v)(b)(2) (Supp. 2011)).

287 *See, e.g.*, *Paul Ryan Said "15 Unelected, Unaccountable Bureaucrats" Could "Lead to Denied Care for Current Seniors,"* POLITIFACT.COM (Aug. 18, 2012), http://www.politifact.com/florida/statements/2012/aug/23/paul-ryan/paul-ryan-said-15-unelected-unaccountable-bureaucr/.

for the elimination of the Independent Payment Advisory Board, which will impose arbitrary across-the-board cuts to physicians and other providers."[288] Hopefully the other reforms in the ACA will make the implementation of the board unnecessary. It would be politically difficult to execute, given past experience with unsuccessful physician payment reductions dictated by the SGR and the consequent annual doc fix would indicate.

F. Health Care Quality Improvements (Title III, Subtitle F)

Subtitle F contains 11 sections establishing various research initiatives on health care quality improvement, which are displayed at Table 12.[289] Section 3501 establishes an extensive health services research agenda for the AHRQ in the Public Health Service.[290] The Director of AHRQ is directed to, "identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care quality, safety, and value."[291]

The Director of AHRQ must also furnish technical assistance to providers in implementing models and practices identified in its research.[292] The remainder of Subtitle F contains a variety of initiatives, such as the exemplary initiative establishing community health teams to support patient-centered medical homes.[293] Research on health care quality improvements, to be funded under this Subtitle and supervised by the Agency for Healthcare Research and Quality, is currently proceeding.

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288 *Independent Patient Advisory Board*, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/advocacy/topics/independent-payment-advisory-board.page (last visited May 30, 2013, 8:30 PM).

289 ACA §§ 3501-3512.

290 *Id.* § 3501 (codified as amended at 42 U.S.C. § 299b–33 (Supp. 2011)).

291 *Id.*

292 *Id.* § 3501 (codified as amended at 42 U.S.C. § 299b–34 (Supp. 2011)).

293 *Id.* § 3502 (codified at 42 U.S.C. § 256a (Supp. 2011)).

Table 12 Subtitle F—Health Care Quality Improvements
Sec. 3501. Health care delivery system research; Quality improvement technical assistance Sec. 3502. Establishing community health teams to support the patient centered medical home Sec. 3503. Medication management services in treatment of chronic disease Sec. 3504. Design and implementation of regionalized systems for emergency care Sec. 3505. Trauma care centers and service availability Sec. 3506. Program to facilitate shared decisionmaking Sec. 3507. Presentation of prescription drug benefit and risk information Sec. 3508. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals Sec. 3509. Improving women's health Sec. 3510. Patient navigator program Sec. 3511. Authorization of appropriations Sec. 3512. GAO study and report on causes of action

G. Protecting and Improving Guaranteed Medicare Benefits (Title III, Subtitle G)

Subtitle G contains two provisions that establish the principle that nothing in the ACA will compromise the guaranteed benefits in the Medicare program. Section 3601 states:

> (a) PROTECTING GUARANTEED MEDICARE BENEFITS.—Nothing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].
>
> (b) ENSURING THAT MEDICARE SAVINGS BENEFIT THE MEDICARE PROGRAM AND MEDICARE BENEFICIARIES.—Savings generated for the Medicare program under title XVIII of the Social Security Act under the provisions of, and amendments made by, this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.[294]

294 *Id.* § 3601.

Section 3602 affirms that the ACA will not cut guaranteed benefits in Medicare Advantage plans, stating "Nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in Medicare Advantage plans."[295] The two sections in this title are simply promises to maintain benefits. The question remains whether these promises can be kept in practice when faced with deficit reduction efforts and funding cuts.

III. IMPROVING TRANSPARENCY AND PROGRAM INTEGRITY (TITLE VI)

Title VI contains measures to improve transparency and program integrity in the Medicare and Medicaid programs. These provisions are displayed in Table 13. Title VI is somewhat of a hodgepodge of provisions. Only Subtitles A, B, D and E actually pertain to the Medicare program.

Table 13
Title VI: Transparency and Program Integrity

Subtitle A—Physician Ownership and Other Transparency
Subtitle B—Nursing Home Transparency and Improvement
Part 1—Improving Transparency of Information
Part 2—Targeting Enforcement
Part 3—Improving Staff Training
Subtitle C—Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-term Care Facilities and Providers
Subtitle D—Patient-Centered Outcomes Research
Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions
Subtitle F—Additional Medicaid Program Integrity Provisions
Subtitle G—Additional Program Integrity Provisions
Subtitle H—Elder Justice Act
Subtitle I—Sense of the Senate Regarding Medical Malpractice

The transparency provisions in Subtitle A of Title IV concern physicians' financial activities with respect to investments in health care enterprises. Subtitle B addresses transparency and fraud and abuse enforcement in nursing homes. Subtitle D establishes an agency and program to conduct patient-centered outcomes research, which is essentially research on the comparative effectiveness of medical treatment modalities and products. Subtitle E contains improvement in existing Medicare, Medicaid, and CHIP program integrity programs. Subtitle E also includes extensive provisions on new procedures screening health care providers.

295 *Id.* § 3602.

A. Physician Ownership and Other Transparency (Title VI, Subtitle A)

The ACA specifically addresses physician ownership of specialty hospitals as well as other physician investments in health care. These provisions are displayed in Table 14. The ACA section 6001 provides that physician-owned hospitals that do not have a provider agreement prior to February 2010 will not be able to participate in Medicare.[296]

Table 14 **Subtitle A—Physician Ownership and Other Transparency**
Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals. Sec. 6002. Transparency reports and reporting of physician ownership or investment interests. Sec. 6003. Disclosure requirements for in-office ancillary services exception to the prohibition on physician self-referral for certain imaging services. Sec. 6004. Prescription drug sample transparency. Sec. 6005. Pharmacy benefit managers transparency requirements.

The remaining sections of Subtitle A establish a transparency reporting program for pharmaceutical and medical device manufacturers with respect to transactions with physicians and teaching hospitals as well as reporting requirements for physicians regarding various ownership and investment interests.[297] This transparency and reporting program responds to concerns that physicians and teaching hospitals receive remuneration from industry, which create conflicts of interest for physicians and teaching hospitals in selecting items and services for patient care.[298]

Although directly related to Medicare, but relevant for all health care payers, the ACA section 6002 imposes new transparency and reporting requirements on suppliers of medical devices and other items about financial transactions with physicians, teaching hospitals and other covered recipients.[299] Specifically, suppliers must report electronically to the Secretary of HHS the following information regarding each transaction: the name and contact information of the

296 *Id.* § 6001 (codified as amended at 42 U.S.C. § 1395nn (Supp. 2011)); *see* David Whelan, *ObamaCare's First Victim: Physician-Owned Specialty Hospitals*, FORBES (Apr. 5, 2010, 4:46 PM), http://www.forbes.com/sites/sciencebiz/2010/04/05/obamacares-first-victim-physician-owned-specialty-hospitals/.

297 ACA § 6002 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)); *see* Robert Steinbrook & Joseph S. Ross, *Transparency Reports" on Industry Payments to Physicians and Teaching Hospitals*, 307 JAMA 1029, 1029-30 (2012).

298 *See* Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 JAMA 429, 430 (2006).

299 ACA § 6002 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

recipient, the date and amount of payment or transfers of value, a description of the form and nature of payment, and whether the payment was related to marketing, education, or research specific to a covered drug, device, biological, or medical supply.[300] The ACA section 6002 also requires manufacturers and suppliers to report any investment and ownership interests of physicians in their organizations.[301] In December 2011, CMS issued a proposed rule to implement Section 6002. A final rule has not been promulgated. By September 2013, CMS must publish "transparency reports" that disclose industry payments on a public website in a search manner.[302]

Pursuant to section 6004, pharmaceutical and medical device manufacturers and suppliers must report any gifts to physicians, physicians groups, or teaching hospitals.[303] The ACA 6004 imposes comparable reporting and transparency requirements on pharmaceutical and medical device manufacturers and suppliers regarding the provision of drug samples.[304] Of more relevance to Medicare specifically, the ACA section 6003 imposes disclosure requirements for physicians with respect to specified medical imaging services excluded for the in-office ancillary services exception to Stark physician self-referral prohibitions.[305] Physicians referring patients to imaging services in which they or members of their practice have investments must notify patients of this interest in writing.[306] Also, the ACA section 6005 requires that pharmacy benefit managers (PBM), or health benefits plans that provide PMB services, which contract with health plans under Medicare or health insurance exchange must report information regarding payment reductions negotiated by the PBM. [307]

The moratorium on expanding the number of physician-owned specialty hospitals in the ACA remains controversial. From a political perspective, the ACA sides with the community hospital, which resents the rise of physician-owned hospitals in attracting lucrative procedures with healthier patients. Physician-owned specialty hospitals might be able to prosper in the future by joining accountable care organizations and finding innovations that promote efficiency and high quality.

The other transparency provisions pertaining to physicians and other health care providers and suppliers require extensive reporting of transactions,

300 *Id.*

301 *Id.*

302 Medicare, Medicaid, Children's Health Insurance Program; Transparency Reports and Reporting of Physician Ownership or Investment Interests; 76 Fed. Reg. 78,742 (Dec. 19, 2011) (to be codified at 42 C.F.R. pts. 402 and 403).

303 ACA § 6004 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

304 *Id.*

305 *Id.* § 6003 (codified as amended at 42 U.S.C. § 1395nn(b)(2) (Supp. 2011)).

306 *Id.* § 6004 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

307 *Id.* § 6005 (codified as amended at 42 U.S.C. § 1395nn(b)(2) (Supp. 2011)).

contributions, and the like, which impose a great burden on physicians, other providers, and manufacturers of pharmaceuticals and medical devices. Of note, CMS has not promulgated the final rule to implement the transparency and reporting requirements on physicians, which may suggest controversy over its contents.

B. Nursing Home Reforms

Subtitle B of Title VI pertains to program integrity measures for nursing homes. Part A of Subtitle B addresses nursing home transparency and improvement. Specifically, the ACA section 6101 requires that skilled nursing facilities under Medicare and nursing facilities under Medicaid make available information on their ownership.[308] They must also implement a compliance and ethics program to promote greater accountability.[309] CMS will also publish information on staffing data, number of complaints, and criminal violations along with data on the Nursing Home Compare Medicare Website.[310] The Secretary of HHS is charged with making other changes to achieve greater nursing home accountability,[311] including the development of a standardized complaint form for beneficiaries.[312] Part 2 of Subtitle B contains provisions to strengthen enforcement.[313] Subtitle C contains measures to improve staff training on dementia and abuse prevention.[314] The Secretary must establish a nationwide program for national and state background checks of direct patient access employees of certain long-term care facilities.[315]

The transparency and program integrity provisions for nursing homes seem to have been implemented with little difficulty or controversy.[316] The nursing home industry is one of the most regulated industries in the United States. However, there have been problems for years with nursing home compliance with regulatory requirements, which the provisions in the ACA are intended to address.[317]

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308 *Id.* § 6101 (codified as amended at 42 U.S.C. § 1320a–3 (Supp. 2011)).

309 *Id.* § 6102 (codified as amended at 42 U.S.C. § 1302a-7k (Supp. 2011)).

310 *Id.* § 6103 (codified as amended at 42 U.S.C. § 1395i–3 (Supp. 2011)).

311 *Id.* §§ 6104-6105 (codified as amended at 42 U.S.C. § 1395yy (Supp. 2011)).

312 *Id.* § 6106 (codified as amended at 42 U.S.C. § 1395yy (Supp. 2011)).

313 *Id.* §§ 6111-6114.

314 *Id.* § 6121.

315 *Id.* § 6201.

316 *See* Guidance on the Nursing Home Transparency Provisions of the Patient Protection and Affordable Care Act, AM. HEALTH CARE ASS'N, http://www.ahcancal.org/facility_operations/survey_certification/Pages/GuidanceNHTransparencyProvisions.aspx (last visited May 30, 2013, 7:50 PM).

317 Kaiser Commission on Medicaid and the Uninsured, Implementation of Affordable Care Act Provisions To Improve Nursing Home Transparency, Care Quality, and Abuse Prevention (Jan. 2013), http://www.kff.org/medicare/upload/8406.pdf.

C. Subtitle D—Patient-Centered Outcomes Research

Of several initiatives to improve the quality and control the cost of health care services in the ACA, the most important is support for comparative effectiveness research through the establishment of the Patient-Centered Outcomes Research Institute (PCORI).[318]

The ACA establishes a new organization for federally funded comparative effectiveness research. The PCORI has a unique structure.[319] It is a private, nonprofit entity organized under the District of Columbia Nonprofit Corporation Act[320] and governed by a public-private sector board of directors appointed by the Comptroller General.[321] It is independently funded through a federal trust fund, contributions from the Medicare program trust funds, and from private health plans and insurers.[322]

The specific duties of the PCORI are straightforward and described in the statute in great detail.[323] The duties all concern developing and executing a research project agenda. Several "duties" pertain to establishing processes to ensure the quality of the research, the proper dissemination of research results, and the transparency and integrity of the research process. The statute is unusually detailed in the degree to which it specifies processes for developing

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318 "Comparative clinical effectiveness research" and "research" are defined in § 6301(a) of the ACA:

> The terms "comparative clinical effectiveness research" and "research" mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

Subparagraph (B) describes the medical products, procedures and services subject to comparative effectiveness research under the act as follows:

> The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

ACA § 6301(a).

319 *See* Eleanor D. Kinney, *Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J. L. & MED. 522 (2011).

320 District of Columbia Code, § 29-401.01.

321 ACA § 6301(a).

322 *Id.* §§ 6301(d)-(e).

323 *Id.* § 6301(a).

methodologies for comparative effectiveness research and other aspects of PCORI's supervision of research.

The ACA imposed several important limits on the use of PCORI comparative effectiveness research.[324] Specifically, the statute provides, "nothing in this section shall be construed . . . to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer . . . ."[325] Nor can the PCORI develop or employ a "dollars-per-quality adjusted life year" or similar measures that discount the value of a life because of disability as a threshold to establish what type of health care is cost effective or recommended.[326] Further, the ACA prohibits CMS, except with complete transparency and with extensive procedural safeguards, from using such measures as a threshold to determine Medicare coverage or reimbursement or in other incentive programs.[327] These limits were imposed to address concerns among patients, consumers, providers, as well as more conservative politicians that the federal government would use the results of comparative effectiveness research to ration health care based on bloodless criteria.

The PCORI and the associated comparative effectiveness research have been controversial initiatives, under the ACA.[328] However, progress in implementation of the Institute has proceeded as planned, and work is underway.[329] As of yet, it is too early to have a definitive contribution to the evidence, and methods of measuring success are still evolving.[330]

D. Medicare, Medicaid, and SCHIP Program Integrity Provisions (Subtitle E)

Subtitle E, which includes extensive provisions on new procedures for screening health care providers, requires the Secretary to establish new, stricter procedures and criteria to screen providers and suppliers who are enrolling or re-enrolling in Medicare, including criminal background checks and finger

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324 *Id.* § 6301(c).

325 *Id.* § 6301(a).

326 *Id.* § 6301(c).

327 *Id.*

328 *See* Eleanor D. Kinney, *The Real Truth about Death Panels: Comparative Effectiveness Research and the Health Reform Legislation*, 36 OKLA. CITY L. REV. 667, 672 (2011).

329 PATIENT-CENTERED OUTCOMES RES. INST.,(PCORI), http://www.pcori.org (last visited Apr. 10, 2013); *see* A. Eugene Washington & Steven H. Lipstein, *The Patient-Centered Outcomes Research Institute—Promoting Better Information, Decisions, and Health*, 365 NEW ENG. J. MED. e31 (2011).

330 Sean D. Sullivan et al., *Comparative Effectiveness Research in the United States: A Progress Report*, 16 J. MED. ECON. 295, 295-97 (2013); Danielle C Lavallee et al., *Stakeholder Engagement in Comparative Effectiveness Research: How Will We Measure Success?* 1 J. COMP. EFFECTIVENESS RES. 397, 397-400 (2012); Eleanor Kinney, *Prospects for Comparative Effectiveness Research under Federal Health Reform*, 21 ANNALS HEALTH L. 79, 82-85 (2012).

printing.[331] These provisions are presented in Table 15. Other matters to be screened are licensure checks, which may include such checks across states, unscheduled and unannounced site visits, database checks, and other screening as the Secretary determines appropriate.[332] They are required to disclose all affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a federal health care program, or has had their billing privileges revoked.[333] They are also required to establish a compliance program that contains the core elements developed by the Secretary in consultation with the OIG.[334]

The ACA section 6402 includes several so-called enhanced Medicare and Medicaid program integrity provisions.[335] These include the integrated data repository claims and payment data from all parts of Medicare, Medicaid, SCHIP, health-related programs administered by the Departments of Veterans Affairs and Defense, the Social Security Administration, and the Indian Health Service which will allow Medicare to access information about the activities of providers in other federal programs.[336] Section 6402 also imposes new penalties on providers or suppliers who make false statements in connection with seeking Medicare payment.[337]

331 ACA § 6401 (codified as amended at 42 U.S.C. § 1395cc(j) (Supp. 2011)); *see Medicare and Medicaid Fraud, Waste, and Abuse: Effective Implementation of Recent Laws and, Agency Actions Could Help Reduce Improper Payments: Hearing Before the S. Comm. on Federal Financial Management, Government Information, Federal Services, and International Security and S. Comm. on Homeland Security and Governmental Affairs*, 112th Cong. 7 (2011) (statement of Kathleen M. King, Dir. Health Care and Kay L. Daly, Dir. Fin. Assurance Mgmt.), *available at* http://www.gao.gov/assets/130/125646.pdf.

332 ACA § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(2) (Supp. 2011)).

333 *Id.* § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(5) (Supp. 2011)).

334 *Id.* § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(8) (Supp. 2011)).

335 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a–7k (Supp. 2011)).

336 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a–7k(a) (Supp. 2011)).

337 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a–7k (Supp. 2011)).

Table 15 Subtitle E—Medicare, Medicaid, and SCHIP Program Integrity Provisions
Sec. 6401. Provider screening and other enrollment requirements under Medicare, Medicaid, and CHIP
Sec. 6402. Enhanced Medicare and Medicaid program integrity provisions
Sec. 6403. Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank
Sec. 6404. Maximum period for submission of Medicare claims reduced to not more than 12 months
Sec. 6405. Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals
Sec. 6406. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse
Sec. 6407. Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare
Sec. 6408. Enhanced penalties
Sec. 6409. Medicare self-referral disclosure protocol
Sec. 6410. Adjustments to the Medicare durable medical equipment, prosthetics, orthotics, and supplies competitive acquisition program
Sec. 6411. Expansion of the Recovery Audit Contractor (RAC) program

Section 6403 of the ACA eliminates duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank, consolidating the two databanks.[338] The Secretary will enhance national health care fraud and abuse data collection program for reporting adverse actions taken against health care providers, suppliers, and practitioners, and submit information on the actions to the National Practitioner Data Bank.

Subtitle E closes with various sections to improve the integrity of the Medicare program. The ACA section 6404 establishes a maximum period for submission of Medicare claims of not more than twelve months.[339] Next, Section 6405 requires physicians who order items or services to be Medicare enrolled physicians or eligible professionals.[340] Section 6406 enhances documentation requirements for physicians on referrals to items or services at high risk of waste and abuse.[341] Subsequently, Section 6407 requires a face-to-face encounter with the patient before physicians may certify eligibility for home health services or durable medical equipment.[342] Section 6408 enhances penalties for violations of the CMPA.[343] In April 2010, CMS promulgated the final rule to implement the

338 *Id.* § 6403 (codified as amended at 42 U.S.C. § 1320a–7 (Supp. 2011)).
339 *Id.* § 6404 (codified as amended at 42 U.S.C. § 1395f(a)(1) (Supp. 2011)).
340 *Id.* § 6405 (codified as amended at 42 U.S.C. § 1395m(a)(11)(B) (Supp. 2011)).
341 *Id.* § 6406 (codified as amended at 42 U.S.C. § 1395u(h) (Supp. 2011)).
342 *Id.* § 6407(a) (codified as amended at 42 U.S.C. § 1395m(a)(11) (Supp. 2011)).
343 *Id.* § 6408 (codified as amended at 42 U.S.C. § 1320a–7a(a) (Supp. 2011)).

enrollment, ordering, referring and documentation retirements.[344] And in February 2011, CMS promulgated the final rule to implement the enrollment screening provisions.[345] The ACA section 6409 requires the Secretary, in cooperation with the OIG, to establish a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the SSA[346] pursuant to a self-referral disclosure protocol.[347] Lastly, the final provisions of Subtitle E pertain to durable medical equipment (DME): expanding the competitive acquisition program for DME and addressing other issues.[348]

The ACA provisions in this subtitle are an important departure from earlier Medicare fraud and abuse authorities. These provisions focus more on fraud prevention and move away from the traditional approach of paying first and recouping payments later. The provisions and the rules thereunder focus on making sure that only legitimate providers are in the program and only legitimate claims are paid. This approach to Medicare fraud and abuse control has been long in coming.

According to the OIG,[349] the reformed fraud and abuse programs have been quite successful in increasing government recoveries in fraud cases and protecting the Medicare program. In 2013, the OIG reported that for every dollar spent on health-care-related fraud and abuse investigations in the last three years, the government recovered $7.90, which is the highest return on investment since the inception of the Fraud and Abuse Control Program.[350] In February 2012, HHS reported that for 2011, federal health care fraud abuse prevention and enforcement efforts recovered nearly $4.1 billion—the largest ever in a single year.[351]

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344 Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements, and Changes in Provider Agreements, 77 Fed. Reg. 25,284 (Apr. 27, 2012) (to be codified at 42 C.F.R. pts. 424 and 431).

345 Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5,862 (Feb. 2, 2011) (to be codified at 42 C.F.R pt. 1007).

346 42 U.S.C. § 1395nn (Supp. 2011).

347 ACA § 6409.

348 *Id.* § 6410 (codified as amended at 42 U.S.C. § 1395w(a) (Supp. 2011)).

349 OIG, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM REPORT: FISCAL YEAR 2010 (2011), *available at* http://org.hhs.gov/publications/doc/hcfac/hcfacreport2012.pdf.

350 *Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud*, DHHS (Feb. 11, 2013), http://www.hhs.gov/news/press/2013pres/02/20130211a.html.

351 *Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly $4.1 Billion: Largest Sum Ever Recovered in Single Year*, DHHS (Feb. 14, 2012), http://www.hhs.gov/news/press/2012pres/02/20120214a.html.

IV. CURBING EXPENDITURES AND MOVING TOWARD A SINGLE-PAYER SYSTEM

The ACA has made many changes in the Medicare program that will strengthen the program and enhance its sustainability. At the very least, these changes will serve as a model for state Medicaid programs and other private payers and thus will constitute a major impetus of health reform for the U.S. health care sector. These changes address the three major problems facing the Medicare program since its inception—cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. They may also prepare the Medicare program to be transformed into a single payer system should other coverage expansions in the ACA fail.

A. Reducing Medicare Expenditures under the ACA

The history of Medicare payment methodologies has been driven by the federal government's struggle to gain control of the cost and volume variables in the fundamental equation for all health care expenditures: Medicare Expenditures = (Cost) x (Volume). By necessity, the original architects of the Medicare program placed the levers controlling the cost of care in the hands of providers. As described in Part III above, in the 1980s and 1990s, the federal government gained control of the cost of and charges for care with IPPS for hospitals and the Medicare Physician Fee Schedule for physicians. These actions were a tremendous first step for the Medicare program, especially in an environment in which physicians and hospitals in which they practiced had tight control over the content of medical care and the definition of its quality.

However, these payment reforms for hospitals and physicians did not address the problem with the high volume of services. Nor did they address the increasingly complex and costly content of health care services or the role of provider entrepreneurialism in the provision of these services. Specifically, entrepreneurial physicians and providers have had great incentives to provide more and arguably unnecessary services even under current Medicare payment methods. CMS' efforts to control volume and expense of physician services proved difficult, if not impossible, as seen with the experience with the Medicare SGR.

As discussed above, the federal government turned to health services research to determine how to measure and assess the quality of care empirically and determine if Medicare expenditures were going for care of good value with respect to outcomes and efficiency. The focus on quality outcomes and other data-driven reforms had created a new environment of accountability for physicians, hospitals, and the entire health care sector. The definition of quality became empirically and statistically-based and was no longer the sole province of physicians. The stage was set for the quality reporting and value-based

purchasing programs of the next century. Also, it became inherently easier for the stewards of the Medicare program to identify unnecessary and unsafe care as data were increasingly available to identify these types of care.

The schematic at Table 2, *supra*, illustrates the focus of the Medicare program's regulation of payment for health care. Medicare payment regulation seeks to prevent fraud and abuse that provides unreasonable or unnecessary care as well as non-existent care. Medicare payment regulation also seeks to reduce care that is inefficient. The ultimate goal of having payment regulation linked to quality measures is to promote care that is reasonable, necessary, and efficient, as determined by established measures of high quality care. Medicare does not want to pay for any unnecessary services, even if they are not harmful to the beneficiaries.

The quality and payment initiatives in Title III of the ACA are designed to achieve these policy goals, as are the transparency and integrity initiatives of Title VI. By making the connection between payment and quality performance, Medicare endeavors to recognize redundant and excess care that is not necessarily abusive, but rather is useless. This is a very important step in Medicare's effort to control the volume of Medicare services and thereby Medicare expenditures.

The trustees of the Medicare trust funds have estimated that ACA will have a positive impact on controlling Medicare expenditures.[352] The Medicare Trust Fund Trustees report states:

> Projected Medicare costs over 75 years are about 25 percent lower because of provisions in the . . . ACA . . . . Most of the ACA-related cost saving is attributable to a reduction in the annual payment updates for most Medicare services (other than physicians' services and drugs) by total economy multifactor productivity growth, which is projected to average 1.1 percent per year . . . . In addition, an almost 30-percent reduction in Medicare payment rates for physician services is assumed to be implemented in 2012, notwithstanding experience to the contrary.[353]

352 *Trustees Announce Solvency of Medicare Trust Fund Extended by 12 Years to 2029*, DHHS (Aug. 5, 2010), http://www.hhs.gov/news/press/2010pres/08/20100805d.html.

353 *Status of the Social Security and Medicare Programs, A Summary of the 2011 Annual Reports*, U.S. SOC. SEC. ADMIN., http://www.ssa.gov/oact/TRSUM/tr11summary.pdf (last accessed Jun. 4, 2013, 11:11 PM).

There are other reports of slowing growth in Medicare and other health care expenditures.[354] Analysts at CMS published an article in leading health policy journal *Health Affairs* describing very encouraging trends in Medicare expenditures and attributing them to the economic conditions since 2008.[355] Specifically, CMS reported that Medicare spending in 2020 is now estimated to be $150 billion lower than the $1.07 trillion projected by CMS if reforms had not been enacted.[356]

B. Curbing Provider and Supplier Entrepreneurialism

The reforms in Titles III and IV are also intended to curb the entrepreneurial impulses of physicians and other providers and suppliers. These entrepreneurial impulses serve to increase the volume of services at great cost to the Medicare program. Medicare program payments are comprised almost exclusively from public funds generated from regressive wage taxes for Part A of the Medicare program, general revenues and beneficiary premiums under Parts B, and D.

Capitalism and free markets are the prevailing economic system in the United States. Under this system, entrepreneurialism among economic actors is generally a good thing as it generates more economic activity. Even if sellers sell items and services to buyers who do not need them is not a problem in a capitalist system. These purchasing decisions are private matters that have no bearing on public policy.

However, such entrepreneurial conduct is not appropriate when supplying items and services to public programs. Nor is appropriate in a situation with market failure where public subsidies are necessary to get needed goods and services to all. Currently, public spending on health constitutes about 45 percent of health care expenditures.[357] Policy makers and economists have long observed that the markets for health care services and health insurance have been in failure for many years due to the fact they rely on massive publish subsidies to meet the needs of all consumers.[358]

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354 John Holahan & Stacey McMorrow, *Medicare and Medicaid Spending Trends and the Deficit Debate*, 367 NEW ENG. J. MED. 393 (2012); Chapin White & Paul B. Ginsburg, Slower Growth in Medicare Spending—Is This the New Normal? 366 NEW ENG. J. MED. 1073 (2012); Karen Davis, *The Commonwealth Fund Blog: What's Working to Control Costs* (Jun. 12, 2012),http://www.commonwealthfund.org/Blog/2012/Jun/Whats-Working-Control-Costs.aspx.

355 Anne B. Martin et al., *Growth in US Health Spending Remained Slow in 2010; Health Share of Gross Domestic Product Was Unchanged from 2009*, 31 HEALTH AFF. 208 (2012).

356 *Id.*

357 Nellie Bristol, *'Big Picture' Financing Study: Public Spending on Health Care Rises to 45 Percent*, COMMONWEALTH FUND, WASH. HEALTH POL'Y WEEK IN REV. (Jun. 1, 2012), http://www.commonwealthfund.org/Newsletters/Washington-Health-Policy-in-Review/2012/Jun/June-4-2012/Public-Spending-on-Health-Care-Rises-to-45-Percent.aspx.

358 Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963); Martin S. Feldstein, *Hospital Cost Inflation: A Study of Nonprofit Price*

Too often health care institutional providers, physicians and insurers, who operate MA plans, and manufacturers and suppliers of medical devices and other items, operate as capitalistic entrepreneurs, seeking to maximize revenues and profits.[359] Such behavior is laudable in a conventional free market, but not in a failed market. Excess demand that does not represent the need for reasonable or necessary items or services is not desirable even if it generates more economic activity. Such demand and meeting that demand translate into unnecessary government expenditures at the taxpayers' expense.

The Medicare fraud and abuse prohibitions in Title VI of the ACA are first and foremost about preventing outright fraud in obtaining money from for the Medicare program. Of note, in February 2012, HHS reported that for 2011, federal health care fraud abuse prevention and enforcement efforts recovered nearly $4.1 billion—the largest ever in a single year.[360]

But the prohibitions serve a larger mission of preventing inappropriate profiteering from the Medicare program through program abuse. Over-prescription of items and services that are not necessary or even marginally necessary for the diagnosis and treatment of illness or injury are abuse. However, this principle is contrary to the theory of capitalistic markets in which the desired amount of items and services that an individual may need or buy depends on individual preferences and actions and there is no normative assessment of the necessity of the items or services. Indeed, in a capitalistic market, providers and suppliers would be rewarded for "creating demand" among consumers for their items and services. Increased sales of these items and services would be applauded, from a public benefit prospective, as a contribution to increased economic activity.

Nevertheless, there is room for entrepreneurialism in the health care sector and the Medicare program. Entrepreneurs who imagine more efficient and effective delivery of health care services for Medicare beneficiaries are welcome and, indeed, invited. The experience to date with the shared savings program and accountable care organizations suggests that providers have engaged in true innovation and advancement with entrepreneurial initiative.

Dynamics, 61 AM. ECON. REV. 853 (1971); Milton I. Roemer, *Market Failure and Health Care Policy*, 3 J. PUB. HEALTH POL'Y 419 (1982).

359 *See* Eleanor D. Kinney, Kinney, *For-Profit Enterprise in Health Care: Can It Contribute to Health Reform?*, 36 AM. J. L. & MED. 405, 420 (2010).

360 *Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly $4.1 Billion: Largest Sum Ever Recovered in Single Year*, DHHS (Feb. 14, 2012), http://www.hhs.gov/news/press/2012pres/02/20120214a.html.

C. Positioning Medicare to Become a Single Payer System

The final and probably unintentional potential benefit of the ACA's Medicare reforms is to facilitate a strong Medicare program that can serve as a single payer system in the event other ACA coverage expansions fail. Of note, Medicare as the basis of a single payer system is hardly a new idea.[361] The Medicare program, with successfully implemented ACA reforms, could easily be transformed into a single payer system if private health insurance were to become inaccessible or unaffordable and/or state Medicaid programs for the poor were to not expand.

Efforts to implement Title I of the ACA which authorizes the creation of state health insurance exchanges for private health insurance are underway.[362] The IRS issues a proposed rule in January 2013 to implement the mandate to purchase insurance.[363] However, smooth implementation in all states is by no means certain.[364] Some evidence suggests that private insurance companies are leaving the health insurance market already.[365] Evidence also suggests that health insurance exchanges may not be large enough to keep premiums low and may in

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361 *See Single-Payer Health Care, Improved Medicare for All*, http://www.medicareforall.org/pages/Explanation (last visited Jun. 4, 2013); *see also* Paul Krugman, *Why Americans Hate Single-Payer Insurance*, N.Y. TIMES (Jul. 28, 2009, 11:45 AM), http://krugman.blogs.nytimes.com/2009/07/28/why-americans-hate-single-payer-insurance/; David Himmelstein & Steffie Woolhandler, *There is a Better Way*, N.Y. TIMES (May 28, 2013, 12:42 PM), http://www.medicareforall.org/pages/Explanation.

362 Health Insurance Market Rules, 78 Fed. Reg. 13,406 (Feb. 27, 2013) (45 CFR Parts 144, 147, 150, 154 and 156); Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18,311 (Mar. 27, 2012) (45 C.F.R. pts. 155, 156, and 157).

363 Shared Responsibility Payment for Not Maintaining Minimum Essential Coverage, Notice of Proposed Rulemaking and Notice of Public Hearing, 78 Fed. Reg. 7314 (Feb. 1, 2013) (26 C.F.R. pt. 1); *see* Michelle M. Mello & I. Glenn Cohen, *The Taxing Power and the Public's Health*, 367 NEW ENG. J. MED. 1777, 1777-79 (2012).

364 *See State Health Exchange Profiles*, KAISER FAM. FOUND. http://healthreform.kff.org/State-Exchange-Profiles-Page.aspx (last accessed Jun. 4, 2013, 10:44 PM); *see Establishing Health Insurance Exchanges: An Overview of State Efforts* (May. 2, 2013), http://www.kff.org/healthreform/upload/8213-2.pdf; *see* Katie Keith et al., *Implementing the Affordable Care Act: State Action on the 2014 Market Reforms* (The Commonwealth Fund, Feb. 2013), http://www.commonwealthfund.org/Publications/Fund-Reports/2013/Jan/State-Action-2014-Market-Reforms.aspx; *see also* Deloitte LPP, Issue Brief: The Impact of Health Reform on the Individual Insurance Market: *A Strategic Assessment* (2011), http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/Health%20Reform%20Issues%20Briefs/us_chs_HealthReformAndTheIndividualInsuranceMarket_IssueBrief_101011.pdf; *see also* Len M. Nichols, *Implementing Insurance Market Reforms Under The Federal Health Reform Law*, 29 HEALTH AFF. 1152 (2010); *see generally* Timothy Stoltzfus Jost, *Health Insurance Exchanges: Legal Issues*, 37 J. L., MED. & ETHICS 51 (2009).

365 The Robert Wood Johnson Found: Issue Brief: Recognizing Destabilization in the Individual Health Insurance Market, (Jul. 2010), http://www.maine.gov/legis/opla/RWJbrief-medlossratio.pdf.

fact lead to increases in premiums and higher payments to providers as competition among insurers may not work as anticipated.[366] There are also credible reports that premiums for private commercial insurance will rise to unacceptable levels. According to the Society of Actuaries:

> [I]nsurers will have to pay out an average of 32 percent more for claims on individual health policies under the Act, a cost likely to be passed on to consumers. By 2017, the estimated increase would be 62 percent for California, about 80 percent in Ohio and Wisconsin, more than 20 percent for Florida and 67 percent for Maryland. The report also predicts the law will reduce the number of Americans without health insurance from 16.6 percent to as low as 6.6 percent after three years.[367]

If the private insurers are unable to provide affordable health insurance coverage through these exchanges, then some kind of public program will be necessary to achieve coverage expansions. Also, the expansion of Medicaid, the other major coverage expansion strategy in the ACA, is in doubt. The Supreme Court of the United States ruled, in *National Federation of Independent Business v. Sebelius*,[368] that the federal government cannot eliminate funding for a state's Medicaid program if the state elects not to adopt the ACA Medicaid expansions. This decision has created uncertainty in whether states will actually proceed with the Medicaid expansion.[369] There is already considerable evidence that many states may not proceed with the expansion, at least not in the near future.[370] There is even discussion of states purchasing private insurance for Medicaid recipients.[371] If states are not required to proceed with federally mandated

366 Dana P. Goldman et al., *Health Insurance Exchanges May Be Too Small to Succeed*, N.Y. TIMES (Nov. 23, 2012, 6:00 AM).

367 *Society of Actuaries Reaches the Same Conclusion as Health Partners America: Rising Costs for Individual Insurance Coverage Plans Under Obama Health Care Law* (Mar. 29, 2013), http://insurancenewsnet.com/article.aspx?id=376941#.UVsBZZNg9KJ.

368 No. 11–393 (June 28, 2012); *see* Timothy S. Jost & Sara Rosenbaum, *The Supreme Court and the Future of Medicaid*, 367 NEW ENG. J. MED. 983 (2012).

369 *The Cost and Coverage Implications of the ACA Medicaid Expansion: National and State-by-State Analysis*, KAISER FAM. FOUND. (Nov. 1, 2012), http://kff.org/health-reform/report/the-cost-and-coverage-implications-of-the/.

370 Benjamin D. Sommers & Arnold M. Epstein, *U.S. Governors and the Medicaid Expansion—No Quick Resolution in Sight* 368 NEW ENG. J. MED. 496, 497-99 (2013); *see also* Benjamin D. Sommers and Arnold M. Epstein, Medicaid Expansion—The Soft Underbelly of Health Care Reform? 363 NEW ENG. J. MED. 2085 (2010).

371 Josh Barro, *When the Affordable Care Act Becomes Unaffordable*, BLOOMBERG NEWS (Mar. 26, 2013, 10:22 AM), http://www.bloomberg.com/news/2013-03-26/when-the-affordable-care-act-becomes-unaffordable.html; Editorial Board, *Using Medicaid Dollars for Private*

expansions under the ACA, there may be greater pressure for the expansion of the Medicare program to cover persons otherwise not covered under the ACA Medicaid expansions.

To ensure the sustainability of the Medicare program as a single payer system, the funding streams that have supported state Medicaid programs and private health insurance should likewise be tapped to fund the Medicare program as a single payer system. Thus, the design of the Medicare program would be a little more complex than simply enrolling people into the program and abolishing the Medicaid program. As indicated in Part II of this article, Medicare is currently financed by a federal wage tax and premiums paid by beneficiaries. State Medicaid programs pay the premiums for their recipients who are otherwise eligible for Medicare. Private employers contribute significantly toward their employees' health insurance. States and private employers should continue to support the Medicare program through payment of premiums for people for whom they are responsible.

The easiest way to transform Medicare into a single payer system is through incremental steps. The first incremental step would be to allow individuals ages 55 to 64 to "buy into" Medicare at a subsidized rate. According to the Kaiser Family Foundation, one in eight people in this age group are uninsured and tend to be in poorer health.[372] This approach was originally part of the ACA, but dropped in order to ensure the support of Senator Joe Lieberman from Connecticut for passage of the ACA.[373] The initiatives in Title III to reorganize medical practice to provide better care for chronically ill patients is important to implement, in order to accommodate these beneficiaries in a cost effective manner.

The next incremental step could be to expand the group of Medicaid recipients who could enroll in Medicare. The Medicare program currently permits states to enroll Medicare eligible Medicaid recipients in Medicare.[374] So-called "dual eligibles" constitute the poorest and sickest group of Medicaid beneficiaries.[375] Historically, dual eligibles have not been served particularly well by either the Medicare or the Medicaid programs as there has been poor

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Insurance, N.Y. TIMES (Mar. 31, 2013), http://www.nytimes.com/2013/04/01/opinion/using-medicaid-dollars-for-private-insurance.html?_r=0.

372 Gretchen Jacobson et al., *Health Insurance Coverage for Older Adults: Implications of a Medicare Buy-In*, KAISER FAM. FOUND. (Nov. 30, 2009) http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7904-02.pdf.

373 Jacob Goldstein, *Why Joe Lieberman Is Opposed to Expanding Medicare*, WALL ST. J. HEALTH BLOG (Dec. 14, 2009, 9:07 AM), http://blogs.wsj.com/health/2009/12/14/why-joe-lieberman-is-opposed-to-expanding-medicare/.

374 42 U.S.C. § 1396 (2006).

375 Katherine Young et al., *Kaiser Commission on Medicaid and the Uninsured: Medicaid's Role for Dual Eligible Beneficiaries*, KAISER FAM. FOUND. (Apr. 1, 2012) http:// kaiserfamilyfoundation.files.wordpress.com/2013/01/7846-03.pdf.

coordination of the two programs in serving duel eligibles.[376] The ACA endeavors to address this problem with the creation of a new office within CMS, the Federal Coordinated Health Care Office, to bring together relevant staff of the Medicare and Medicaid programs at CMS to more effectively integrate benefits under the two programs and improve the coordination between the federal government and states to ensure that dual eligibles get the benefits of both programs.[377] The ACA contains other provisions that would facilitate the participation of dual eligibles in the reforms to improve quality and efficiency of care in Title III.[378]

This effort to integrate and coordinate benefits under the two programs for dual eligibles is an essential step in moving Medicare to a single payer system. To promote sustainability of the Medicare single payer system, it would be desirable to have states participate financially and administratively. States would pay the premiums for Medicaid beneficiaries for Parts B and D as they do now for duel eligibles. They could also operate continue to operate their health plans for Medicaid recipients as they do now. States already have extensive administrative assets devoted to the Medicaid program that would be greatly benefit the administration of a Medicare single payer system at the state level.

The final step toward making the Medicare program into a single payer system would be to establish Medicare as a public option plan that would be available to any person through state health insurance exchanges. A public option was originally in the health reform bill that passed the House.[379] It was dropped in the bill finally passed in the Senate, primarily on ideological grounds.[380] The original public option in the health care reform legislation created a public plan that would meet the conditions for health insurance plan requirements established for health insurance exchange but not through the Medicare statute.

It would be more efficient to establish a public option directly through the Medicare program with the enactment of Part E of the Medicare program. Part E could be available for any person who elected to join the plan and would operate the same way as Medicare works now. Beneficiaries could elect traditional fee-

376 Judy Kasper et al., *Chronic Disease and Co-Morbidity Among Dual Eligibles: Implications for Patterns of Medicaid and Medicare Service Use and Spending*, KAISER FAM. FOUND. (Jul. 10, 2010), http://www.kff.org/medicaid/upload/8081.pdf.

377 ACA § 2602.

378 *Affordable Care Act Provisions Relating to the Care of Dually Eligible Medicare and Medicaid Beneficiaries* (May 30, 2011), KAISER FAM. FOUND. http://www.kff.org/healthreform/upload/8192.pdf.

379 ACA §§ 321-331.

380 Helen A. Halpin & Peter Harbage, *The Origins And Demise of The Public Option*, 29 HEALTH AFF. 1117, 1119 (2010); *see* James Brasfield, *The Politics of Ideas: Where Did the Public Option Come from and Where Is It Going?*, 36 J. HEALTH POL., POL'Y & L. 455 (2011); *see also* Theodore Marmor & Jonathan Oberlander, *The Patchwork: Health Reform, American Style*, 72 SOC. SCI. & MED. 125 (2011).

for-service Medicare or join Medicare Advantage plan. Beneficiaries could join Part D prescription drug plans as needed. Also, establishing Medicare Part E as a public option would facilitate contributions from employers. The ACA already has provisions requiring the contributions from larger employers.[381]

A provision allowing Medicaid beneficiaries to enroll in Medicare and be treated as dual eligibles could also be added to Part E, to assist states with the anticipated high cost of Medicaid expansions by transferring part of the responsibility for paying for care from state Medicaid programs to Medicare. Such an approach might help the coverage expansions that were anticipated in ACA Title II, and thwarted by the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, to finally become a reality.

CONCLUSION

When considering issues such as which provisions of the ACA are likely to be successful, needed, or improved, thinking incrementally is appropriate. Moving forward, policy reformers should focus on what changes might be made to the Medicare program in the next budget cycle or legislative year, as most Medicare initiatives are long-term projects that are tweaked annually in the "muddling through" policy-making process. Also, CMS generally conducts evaluations of larger policy initiatives to determine their value empirically.

In sum, a strong Medicare program, made stronger with the ACA reforms to improve quality and efficiency (through Title III) as well as promote transparency and program integrity (through Title VI), stands ready to be the health insurer of all Americans. At the very least, the ACA Medicare reforms will hopefully make the current program more efficient and fiscally sustainable. Certainly improving health care through reforming Medicare is a better approach to assuring health security for the elderly and disabled than approaches that disengage the government as a payer from the health care sector and let people fare alone as health care costs continue to escalate and access to care is compromised.

381 ACA §§ 1511-1515.

No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes

Jordan Paradise, J.D. *

ABSTRACT:

The adverse effects of smoking have fostered a natural market for smoking cessation and smoking reduction products. Smokers attempting to quit or reduce consumption have tried everything: "low" or "light" cigarettes; nicotine-infused chewing gum, lozenges, and lollipops; dermal patches; and even hypnosis. The latest craze in the quest to find a safer source of nicotine is the electronic cigarette. Electronic cigarettes (e-cigarettes) have swept the market, reaching a rapidly expanding international consumer base. Boasting nicotine delivery and the tactile feel of a traditional cigarette without the dozens of other chemical constituents that contribute to carcinogenicity, e-cigarettes are often portrayed as less risky, as a smoking reduction or even a complete smoking cessation product, and perhaps most troubling for its appeal to youth, as a flavorful, trendy, and convenient accessory.

The sensationalism associated with e-cigarettes has spurred outcry from health and medical professional groups, as well as the Food and Drug Administration (FDA), because of the unknown effects on public health. Inhabiting a realm of products deemed "tobacco products" under recent 2009 legislation, e-cigarettes pose new challenges to FDA regulation because of their novel method of nicotine delivery, various mechanical and electrical parts, and nearly nonexistent safety data. Consumer use, marketing and promotional claims, and technological characteristics of e-cigarettes have also raised decades old questions of when the FDA can assert authority over products as drugs or medical devices. Recent case law restricting FDA enforcement efforts against e-cigarettes further confounds the distinction among drugs and medical devices, emerging e-cigarette products, and

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traditional tobacco products such as cigarettes, cigars, and smokeless tobacco.

This Article investigates the e-cigarette phenomenon in the wake of the recently enacted Family Smoking Prevention and Tobacco Control Act of 2009 (TCA). It examines the tumultuous history of attempts at tobacco regulation by reflecting on the history of Congressional activity to regulate tobacco sales and promotion. Furthermore, this Article suggests a feasible approach to strengthening regulation of e-cigarettes under the existing statutory framework. This approach includes increased scrutiny of manufacturer and distributor claims that trigger drug and medical device provisions, utilization of new tobacco product and modified risk tobacco product provisions, and promulgation of new FDA regulations and guidance specifically directed at e-cigarettes.

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INTRODUCTION

The American public conscience has wrestled with knowledge of the adverse effects of smoking for decades, perpetuating an embattled division in the United States between smokers (and those who believe smoking is a personal freedom) and non-smokers (and those who believe that the public health risks and resulting health care costs outweigh personal freedom arguments). In response to the negative health effects of tobacco products and cigarettes in particular, a natural market for smoking cessation and smoking reduction products has emerged over the last 30 years. Those attempting to quit or reduce consumption have tried everything: "low" or "light" cigarettes; nicotine-infused chewing gum, lozenges, and lollipops; dermal patches; and even hypnosis. Regardless of one's position on the personal freedom argument, smoking is not only dangerous to health, it is an addiction—the human body becomes dependent on nicotine through a variety of mechanisms.

The latest craze in the quest to find a "safer" source of nicotine is the electronic cigarette. Electronic cigarettes (e-cigarettes) have swept the market, reaching a rapidly expanding international consumer base. They are composed of three basic standardized parts: the nicotine cartridge; the atomizer, which vaporizes the nicotine; and the battery that powers it.[1] Boasting the tactile feel of a traditional cigarette and rapid nicotine delivery without the dozens of other chemical constituents that contribute to the carcinogenicity of traditional cigarettes and cigarette smoke,[2] e-cigarettes are often portrayed as "safer" than traditional cigarettes, as a smoking reduction or even a complete smoking cessation product, and perhaps most troubling for its appeal to youth, as a flavorful, trendy, and convenient accessory.

The broad appeal of e-cigarettes is skyrocketing given the now incontrovertible scientific evidence of the destructive impacts of smoking on public health, including a consistent statistic that smoking accounts for

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1 Tobacco Fact Sheet: Electronic Cigarettes (E-Cigarettes), Legacy for Longer Healthier Lives, http://www.legacyforhealth.org/content/download/582/6926/version/4/file/Fact_Sheet-eCigarettes.pdf (last updated Dec. 2012).

2 U.S. Surgeon Gen., A Report of the Surgeon General: How Tobacco Smoke Causes Disease—The Biology and Behavioral Basis for Smoking-Attributable Disease Fact Sheet, U.S. Dep't Health & Human Servs., http://www.surgeongeneral.gov/library/reports/tobaccosmoke/ factsheet.html (last visited Apr. 5, 2013).

nearly 5.4 million cancer-related deaths worldwide each year,[3] including approximately 443,000 in the United States.[4] The attraction to e-cigarettes crosses many segments of the population: the heavy smoker wanting to quit or significantly cut back on cigarettes or nicotine use, the occasional smoker seeking a healthier alternative, the smoker seeking a legal way to get a nicotine fix in public places with smoking bans, the non-smoker who wants to try e-cigarettes for the nicotine without the harmful additives, and even the young hipster who wants to complete her technological portfolio with a sleek and popular device that looks and feels like a real cigarette, but brings with it an "atomizer" and celebrity endorsements. The use of e-cigarettes is on the rise—with group identity to "vaping"[5]—and is becoming a strong presence in various social media outlets and easy product purchasing online through distributors and affiliates or at convenience stores and retail establishments.

However, the sensationalism associated with e-cigarettes has spurred outcry from health and medical professional groups, as well as the Food and Drug Administration (FDA), because of the unknown effects on public health and an absent safety profile. Inhabiting a realm of products deemed "tobacco products" under recent 2009 legislation and subsequent case law,[6] e-cigarettes pose new challenges to FDA regulation because of their novel method of nicotine delivery, various mechanical and electrical parts, and nearly nonexistent safety data. Consumer use, marketing and promotional claims, and technological characteristics of e-cigarettes have also raised decades-old questions of when the FDA can assert authority over products as drugs or medical devices.

In the wake of the recently enacted Family Smoking Prevention and Tobacco Control Act (TCA), it is urgent to examine the scope and limitations of the legislative provisions as applied to the recent phenomenon of e-cigarettes. This Article will argue that the recent 2010 D.C. Circuit case *Sottera, Inc. v. FDA*[7] has hindered FDA attempts to regulate products that

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3 Tobacco Free Initiative: Tobacco Facts, WHO, http://www.who.int/tobacco/mpower/tobacco_facts/en/index.html (last visited Apr. 5, 2013).

4 CDC, Current Cigarette Smoking Among Adults—United States, 2011, 309 JAMA 539, 539-40 (2013).

5 Users refer to the process of vaporizing the nicotine within the electronic cigarette as "vaping." *See, e.g.*, Linda Hurtado, Some Say "Vaping" E-Cigarettes is Worse Than Smoking the Real Thing, ABC News (Aug. 16, 2011), http://www.abcactionnews.com/dpp/news/health/some-say-vaping-e-cigarettes-is-worse-than-smoking-the-real-thing.

6 Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

7 *Id.*

fall outside the traditional realm of cigarettes and smokeless tobacco, thwarting Congressional purpose and introducing the potential for significant future public harm. However, despite the *Sottera* decision, the FDA retains powers to proceed against e-cigarettes, including drug and medical device provisions within the Food, Drug, and Cosmetic Act (FDCA), tobacco product provisions of the TCA (integrated into the FDCA) regarding new tobacco products and modified-risk tobacco products, and authority to promulgate product-specific regulations.

This Article does not condemn e-cigarettes, but propels the regulatory discussion forward. The Article proceeds in six parts, providing both a descriptive and prescriptive analysis of the FDA authority to regulate e-cigarettes after *Sottera*. Part I briefly examines fundamental issues of smoking, nicotine addiction, and the public health. Part II examines the tumultuous history of attempts at tobacco regulation by reflecting on the history of Congressional activity to regulate tobacco advertising and promotion, and particularly the monumental 2000 Supreme Court decision *FDA v. Brown & Williamson Tobacco Co.*,[8] which struck down the FDA's assertion of jurisdiction over cigarettes using drug and medical device frameworks. Part III analyzes the legislative provisions and overarching authority imparted to the FDA over tobacco products contained in the TCA. Part IV examines e-cigarettes and industry characteristics, various marketing and promotional tactics, public perceptions about the products, and public health perspectives and scientific studies. Part V examines the culmination of the FDA's attempts to regulate e-cigarettes in *Sottera* and highlights its present position on jurisdiction over these products. Part VI suggests a feasible approach for strengthening FDA regulation of e-cigarettes. The Part also discusses the importance of the scope of intent and intended use in marketing and advertising of the FDCA, the application of the drug and device provisions of the FDCA and the new product and modified-risk product provisions of the TCA, and the opportunity for the development of product-specific requirements through FDA regulations and guidance.

I. ADDICTION, NICOTINE, AND THE PUBLIC HEALTH

Scientists, health and medical professionals, regulators, policymakers, health advocates, and various other stakeholders have devoted tomes to the health effects of smoking and use of tobacco products. The Centers for Disease Control and Prevention (CDC) report that smoking costs the United

[8] 529 U.S. 120 (2000).

States an estimated $96 billion annually in direct medical expenses and an additional $97 billion in lost productivity.[9] This Article does not endeavor to reprise that literature, but only to touch on foundational theories of nicotine addiction and public health. The arguments contained in the Article stem from the position that nicotine itself is a dangerous substance because of its addictive qualities. Efforts to temper current cigarette and tobacco use should be encouraged; therefore, e-cigarettes may be less harmful for heavy or moderate smokers because they may reduce exposure to carcinogens and other toxic chemicals that cause serious disease and death. However, any use of products that contain pure nicotine[10] is potentially harmful based on theories of addiction and dependence. There are a multitude of risks that deserve consideration when contemplating appropriate regulation including the need for premarket assessment for product safety, restrictions on access, appropriate scope of advertising and promotion, and assurance of truthful and non-misleading labeling of such products.

Among other reasons, smokers smoke for the nicotine. Nicotine addiction is characterized as a form of drug dependence recognized in the current edition of the American Psychological Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-IV).[11] The most common form of nicotine delivery is the cigarette, which contains hundreds of toxic chemicals—69 of which have been found to cause cancer.[12] Tobacco smoke itself is a human carcinogen.[13] The cigarette (or cigar, cigarillo, or smokeless tobacco) is merely a conduit, a delivery vehicle for the nicotine contained within the tobacco. Aside from the carcinogenic and toxic effects of tobacco, smokers become addicted to the nicotine.[14]

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[9] CDC, Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004, 57 MORBITY & MORTALITY WKLY. REP., 1226, 1226-28 (2008).

[10] The products contain other ingredients as well, including propylene glycol, ethanol, glycerol (glycerin), acetylpyrazine, guaiacol, myosmine, and cotinine. *See, e.g.*, *FAQs*, NJOY, http://www.njoy.com/pages/FAQs.html (last visited Apr. 5, 2013).

[11] AM. PSYCHOLOGICAL ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS: DSM-IV-TR (4th ed. text rev. 2000); *see, e.g.*, Neal L. Benowitz, *Neurobiology of Nicotine Treatment Addiction: Implications for Smoking Cessation Treatment*, 121 AM. J. MED., at S3, S4 (Supp. 2008); Caroline Cohen et al., *CB1 Receptor Antagonists for the Treatment of Nicotine Addiction*, 81 PHARMACOLOGY BIOCHEMISTRY & BEHAV. 387, 388 (2005).

[12] U.S. Surgeon Gen., *supra* note 2.

[13] *Id.*

[14] *See generally*, Neal L. Benowitz, *Nicotine Addiction*, 362 NEW ENG. J. MED. 2295 (2010); John A. Dani & Steve Heinemann, *Molecular and Cellular Aspects of Nicotine*

Decades of research identify the neural and pharmacologic basis of nicotine addiction induced by smoking. Inhaled smoke carries nicotine into the lungs where it is absorbed and enters arterial circulation.[15] It then flows into the brain, where it binds to nicotinic cholinergic receptors and releases various neurotransmitters.[16] Dopamine, a monoamine neurotransmitter, signals pleasure to the user, while also simultaneously reducing stress and anxiety.[17] "[N]icotine addiction is a combination of positive reinforcements, including enhancement of mood and avoidance of withdrawal symptoms."[18] Conditioning has a secondary role in nicotine addiction: smokers associate particular cues (e.g., social situations, environmental factors, moods) with the high of smoking, often causing relapse when those seeking to quit smoking are confronted with those cues.[19]

Society generally imparts an assumption of risk and right of personal choice on the person using potentially harmful products such as illicit drugs, alcohol, and other common vices.[20] However, smoking introduces measurable harmful effects on third parties exposed to secondhand smoke.[21] Smoking bans and restrictions on use are directed at curbing this secondhand exposure to tobacco smoke in public places and workplaces. Recent studies have also begun to highlight lingering "thirdhand" smoke that remains as residue in carpeting, walls, and other structures for up to 30 years and is potentially toxic, particularly to children climbing, crawling, or playing in or on the contaminated areas.[22]

While nicotine use and addiction have long been linked to tobacco use and smoking of traditional tobacco products such as cigarettes, cigars, and

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Abuse, 16 NEURON 905 (1996); Dorothy K. Hatsukami et al., *Tobacco Addiction*, 371 LANCET 2027 (2008); Steven R. Laviolette & Derek van der Kooy, *The Neurobiology of Nicotine Addiction: Bridging the Gap from Molecules to Behaviour*, 5 NATURE REV. NEUROSCIENCE 55 (2004).

[15] Benowitz, *supra* note 14, at 2295.

[16] *Id.* at 2295-96.

[17] *Id.* at 2298.

[18] *Id.*

[19] *Id.*

[20] *See, e.g.*, Jim Leitzel, Regulating Vice: Misguided Prohibitions and Realistic Controls 3-10 (2008); Smoking: Risk, Perception & Policy (Paul Slovic ed., 2001).

[21] Unfiltered: Conflicts over Tobacco Policy and Public Health 21-27 (Eric A. Feldman & Ronald Bayer eds., 2004).

[22] Ware G. Kuschner et al., Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider, 4 INT'L J. GEN. MED. 115, 118-19 (2011).

smokeless tobacco, e-cigarettes are raising similar health and safety considerations. One attraction to e-cigarettes is that they do not burn tobacco and other harmful chemicals, but instead vaporize nicotine into a fine mist that is inhaled by the user. As discussed in Part IV, however, these products may directly pose a health threat to users given the available levels of nicotine, the lack of cues that serve to signal the end of a typical cigarette, and the potential for electrical components in the products to malfunction. E-cigarette cartridges contain up to twenty times the nicotine of a single cigarette, and the process of vaping lacks the normal cues associated with cigarette completion, such as the butt of the cigarette ending a dose.[23] Furthermore, e-cigarettes are manufactured from metal and ion components that introduce concerns about faulty products and malfunctions. The research on whether vaping e-cigarettes has a detrimental secondhand effect is currently inconclusive; state and local restrictions on e-cigarette use are driven largely by the concern that they have similar damaging effects on bystanders as traditional cigarettes.

Together with general safety concerns, e-cigarettes also have a different risk profile than traditional cigarettes. Although the risks of e-cigarette use are likely less than traditional cigarettes for heavy or moderate smokers, e-cigarettes may also attract regular users who otherwise were social smokers or non-smokers. Measures of a product's overall safety are driven by a risk-benefit analysis: heavy or moderate smokers (and those exposed to their secondhand smoke) would benefit from reducing or eliminating the risks of cigarette use (including lung cancer, heart attack, stroke, adverse pregnancy, and sudden death).[24] Yet those who would not smoke a cigarette, and vulnerable populations such as youth and adolescents, carry a different risk profile. Non-smokers or social smokers who begin using e-cigarettes are exposed to the addictive qualities of nicotine and possible other harmful chemicals present in trace amounts. In addition to the compelling likelihood of e-cigarettes supporting or inducing nicotine addiction in users, and possibly serving as a gateway product for subsequent cigarette use, these products raise a host of potential health and safety problems that have yet to be fully explored.

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[23] *See infra* Part IV.C.

[24] U.S. Surgeon Gen., *supra* note 2.

II. THE HISTORY OF TOBACCO REGULATION AND THE LEGACY OF FDA V. BROWN & WILLIAMSON TOBACCO CO.

A. The Awakening

The tobacco industry has enjoyed a spectacular run. As a longstanding cash crop in the United States and abroad, tobacco leaves and their products have long thrived in the marketplace. Historical research reveals that tobacco has been cultivated since 5000 BC and was widely used in the Americas by the time Columbus reached their shores in 1492.[25] Prior to scientific advancements in toxicology and carcinogen research, little was known about the constituents comprising tobacco products sold primarily in the form of rolled cigars and cigarettes, chewing snuff, and pipe tobacco. It was not until the U.S. Surgeon General's declaration in 1957 that a causal connection had been discovered between smoking and lung cancer that the adverse health effects of smoking began to confront the American public.[26] In 1964, the Surgeon General's subsequent *Smoking and Health* report presented striking statistics supporting the position that smoking was a leading cause of preventable death.[27] Data indicated that by 1964 there had already been 12 million premature deaths attributable to smoking in the United States alone.[28] Subsequent data released in federal government reports revealed a definitive link between nicotine dependence and neurological chemistry of the brain, with addictive effects similar to those of heroin and cocaine.[29]

Shortly after the 1964 report, Congress began enacting legislation restricting various aspects of tobacco industry labeling and advertising practices. Six core statutes were enacted by Congress between 1965 and 2000: the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965;[30] the Public Health Cigarette Smoking Act of 1969;[31] the Alcohol and

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[25] Arthur W. Musk & Nicholas H. De Klerk, *History of Tobacco and Health*, 8 RESPIROLOGY 286, 286 (2003).

[26] The Reports of the Surgeon General: Brief History, NAT'L LIBRARY MED., http://profiles. nlm.nih.gov/ps/retrieve/Narrative/NN/p-nid/58 (last visited Apr. 5, 2013).

[27] Advisory Comm., U.S. Dep't of Health, Educ. & Welfare, Smoking and Health (1964).

[28] *Cancer Facts and Figures 2010*, AM. CANCER SOC'Y 42 (2010), http://www.cancer.org/ acs/groups/content/@nho/documents/document/acspc-024113.pdf.

[29] Office of the Surgeon Gen., U.S. Dep't of Health & Human Servs., The Health Consequences of Smoking: Nicotine Addiction 6-9, 145-239 (1988).

[30] Federal Cigarette Labeling and Advertising Act, Pub. L. 89-92, 79 Stat. 282 (1965).

Drug Abuse Amendments of 1983;[32] the Comprehensive Smoking Education Act of 1984;[33] the Comprehensive Smokeless Tobacco Health Education Act of 1986;[34] and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992.[35] These statutes did not ban or limit cigarettes and smokeless tobacco products, but only restricted particular aspects of industry representations in order to ensure that consumers were aware and informed of the adverse health effects.[36]

Faced with increasing evidence of smoking's ill effects, health care professionals and consumer safety groups submitted various citizens' petitions to the FDA urging the agency to regulate cigarettes and tobacco products based on its overriding public health mission to protect consumers from unsafe products.[37] As data accumulated over the next several decades, so did demands (and petitions) for FDA action.[38] Despite the mounting evidence of the dangers of smoking, FDA Commissioners throughout the end of the 20th century continued to deny these petitions and to toe the line that they lacked the authority to regulate.[39]

B. Commissioner Kessler's 1996 Regulations

Former FDA Commissioner David Kessler announced a new position in August 1996[40] in an effort to remedy FDA inaction in the face of a public health epidemic brought about by smoking and secondhand smoke. Through the process of notice and comment rulemaking, the FDA issued two final rules asserting jurisdictional authority over tobacco products on the basis

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[31] Public Health Cigarette Smoking Act, Pub. L. No. 91-222, 84 Stat. 87 (1969).

[32] Alcohol and Drug Abuse Amendments, Pub. L. No. 98-24, 97 Stat. 175 (1983).

[33] Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984).

[34] Comprehensive Smokeless Tobacco Health Education, Pub. L. No. 99-252, 100 Stat. 30 (1986).

[35] Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, 106 Stat. 394 (1992).

[36] For a detailed description of the scope and chronology of these statutes, see FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 148-56 (2000).

[37] *Id.* at 152-56.

[38] *Id.*

[39] *Id.* at 156.

[40] Supreme Court precedent confirms the ability of an agency to change a position relating to statutory interpretation, no matter how long-standing, as long as it supplies a reasoned analysis and the new position conforms to the statute. *See* Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29 (1983).

that nicotine is a drug[41] and classifying cigarettes and smokeless tobacco as combination drug and medical device products,[42] triggering premarket safety and efficacy requirements provided in the FDCA. This was a controversial move, to say the least.

The FDCA is the voluminous statute granting the FDA jurisdictional authority over various products, including food, cosmetics, animal and human drugs, medical devices, and radiological products.[43] Drugs are defined in the FDCA as (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article.[44]

A device is similarly defined by its intended use, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[45]

Kessler reasoned that because nicotine was an addictive substance affecting the "structure or function of the body" and had significant

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[41] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,419 (Aug. 28, 1996) (to be codified in scattered sections of 21 C.F.R.).

[42] *Id.* at 44,396-44,618. The proposed rule was published in August 1995. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (Aug. 11, 1995).

[43] Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified with some differences in language at 21 U.S.C. §§ 301-399f (2006)).

[44] 21 U.S.C. § 321(g) (2006).

[45] *Id.* § 321(h).

pharmacological effects, it fell under the FDA's statutory authority[46] as a drug[47] and, furthermore, cigarettes and smokeless tobacco were delivery devices.[48] The FDA deemed the "psychoactive, or mood-altering, effects on the brain"[49] "intended"[50] for purposes of the FDCA because they "are so widely known and foreseeable"[51] that manufacturers have deliberately designed cigarettes to provide these effects to consumers.[52]

Based on its newly announced jurisdictional authority, the FDA promulgated a 223-page final rule targeted toward reducing tobacco consumption among children and adolescents.[53] The regulations focused on labeling, promotion, and access to cigarettes and smokeless tobacco by children and adolescents. Provisions included age and photo identification requirements for purchase, prohibitions on free samples, prohibitions on promotional items bearing a brand name, prohibitions on purchases by means of self-service displays or vending machines (except in adult establishments), restrictions on print advertisements to black and white text only, limitations on outdoor advertising near public schools or playgrounds, and prohibitions on brand name sponsorship.[54] The rulemaking has been described as the longest in FDA history with 700,000 comment submissions received during the course of agency considerations.[55]

The final rule further required cigarette and smokeless tobacco

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[46] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,631. This position utilizes the definition of drug as a product "intended to affect the structure or function of the body." 21 U.S.C. §321(g) (Supp. 2011).

[47] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,397.

[48] *Id.* at 44,402.

[49] *Id.* at 44,631-32.

[50] Intent and intended use is the underlying trigger for drug regulation under the FDCA. *See infra* Part III.B.

[51] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,687.

[52] *Id.*

[53] *Id.* at 44,418.

[54] *Id.* at 44,396.

[55] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., COMPLIANCE WITH REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS [REVISION TO DRAFT GUIDANCE] 2 (2011) (citing 155 Cong. Rec. S6407 (June 10, 2009) (statement of Sen. Kennedy)).

manufacturers to submit reports of adverse events to the FDA.[56] The FDA indicated that this regulatory scheme would "achieve[] the best public health result for these products."[57]

While many health professionals lauded the regulations, the FDA was simultaneously rebuked for not going far enough to remove the products from the market.[58] Citing the touchstone risk-benefit assessment underpinning its decisions regarding safety[59] in the drug and medical device realm,[60] the FDA emphasized that due to the potential for consumer withdrawal and large-scale addiction treatment needs, as well as the likely emergence of a black market for banned products, it would closely assess, though not entirely ban, tobacco.[61]

The change in agency position provoked extensive criticism from the tobacco industry. A consortium of tobacco manufacturers, retailers, and advertisers swiftly filed suit alleging that the FDA lacked the jurisdiction to regulate tobacco products, that the FDA did not have authority to promulgate the regulations under the FDCA,[62] and that the restrictions on

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[56] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,615.

[57] *Id.* at 44,413.

[58] *See, e.g.*, Shankar Vedantam, *Clinton Clamps Down on Tobacco*, FRESNO BEE, August 24, 1996, at A1.

[59] While the term "safety" is never defined within the FDCA, the FDA has interpreted it to be based on a risk-benefit assessment, where a product's benefits must outweigh its risks in order for it to be approved to enter the market. The FDA evaluates new drugs based on information provided in the New Drug Application, including the clinical trial data, intended use, patient population, dosage and administration, adverse effects, contraindications, etc. An FDA Commissioner has described the inquiry into risk as depending on a variety of factors, including "[t]he interaction of the drug with body processes," "[t]he manner in which the drug is absorbed, distributed in body tissues, and excreted," "[w]hether active compounds arise from the metabolism of the drug by the body," [t]he influence of other chemicals, such as other drugs or even articles of food or drink upon the activity of the drug in question," and "how the activity of the drug in animals compares with its activity in man." *Drug Safety: Hearings Before a Subcomm. of the H. Comm. on Gov't Operations*, 88th Cong. 566 (1964) (testimony of George Larrick, Comm'r, FDA).

[60] Requirements for drugs and medical devices and the combination product paradigm are detailed elsewhere. *See, e.g.*, Jordan Paradise, *Reassessing Safety for Nanotechnology Combination Products: What Do Biosimilars Add to Regulatory Challenges for FDA?*, 56 ST. LOUIS L. J. 465, 478-90, 494-96 (2012).

[61] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398.

[62] The FDA had asserted authority to promulgate regulations under 21 U.S.C. §360j, which deals with restricted medical devices. Regulations Restricting the Sale and Distribution

advertising violated the First Amendment.[63] The Fourth Circuit held that Congress had not granted jurisdiction to the FDA to regulate tobacco products, thereby bringing an abrupt end to the FDA's short-lived victory over the tobacco industry.[64]

C. Cigarettes and the Supreme Court

The Supreme Court affirmed the Fourth Circuit in a 5-4 decision in *FDA v. Brown & Williamson Tobacco Co.*[65] holding that Congress had clearly "intended to exclude tobacco products from the FDA's jurisdiction."[66] Invoking *Chevron U.S.A. v. Natural Resources Defense Council*,[67] the Court gave no deference to the FDA's 1996 final rules and instead divined a congressional intent to exclude tobacco products from FDA jurisdiction: "reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain the Congress has not given the FDA the authority to regulate tobacco products as customarily marketed."[68]

Crucial to Justice O'Connor's majority opinion was the fact that the FDCA was enacted on the premise that all drugs and devices overseen by the FDA must satisfy hurdles of both safety and efficacy requirements before entering the market. O'Connor reasoned that, given the scientific evidence linking smoking to cancer and other health risks, the danger inherent in cigarettes would necessitate that the FDA remove them completely from the market, a result that Congress surely did not intend.[69]

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of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,399.

[63] Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374 (M.D.N.C. 1997), *rev'd sub nom.* Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000). The district court held that the FDA had authority to regulate tobacco products and to promulgate regulations regarding labeling and access, but that the promotion and advertising restrictions contained within the regulations exceeded statutory authority. *Id.* at 1380-1400.

[64] *Brown & Williamson*, 153 F.3d 155. The court did not reach First Amendment questions.

[65] 529 U.S. 120.

[66] *Id.* at 121.

[67] 467 U.S. 837 (1984). This case sets forth an analytical framework for courts regarding deference to federal administrative agencies in the interpretation of statutes that they administer.

[68] Brown & Williamson, 529 U.S. at 161.

[69] *Id.* at 121-22.

The decision states,

[i]n its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding . . . and . . . device classification . . . provisions.[70]

A powerful dissent trails the majority opinion, highlighting both the basic purpose and the literal language of the FDCA together with the compelling evidence linking cigarettes to pharmacological addiction. In his dissent, Justice Breyer (joined by Justices Stevens, Souter, and Ginsburg) argues:

Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are "intended to affect" the body's "structure" and "function," in the literal sense of these words.[71]

After the decision, the FDA withdrew the regulations.

Brown & Williamson is infamous not only for its outcome, but also for the strained and tortuous application of the legendary two-step test first espoused in *Chevron*[72] to determine whether a court should afford deference to an administrative agency decision interpreting a statute that it administers.[73] The *Brown & Williamson* decision examined the unique history of tobacco including the multitude of statutory schemes and federal agencies charged with particular aspects of tobacco regulation, the FDA's

[70] *Id.* at 121.

[71] *Id.* at 162 (Breyer, J., dissenting).

[72] 467 U.S. 837. *Chevron* involved regulations promulgated by the Environmental Protection Agency (EPA) under the authority of the Clean Air Act of 1977. By regulation, the EPA set forth a definition of a "source" of air pollution, which was upheld by the Court as a permissible reading of the statute. *Id.* at 840, 866.

[73] These two steps are: (1) whether Congress has directly spoken on the precise question at issue in front of the court (i.e., is the statute unambiguous?); and (2) if the statute is silent or ambiguous, the court will defer to the agency's reasonable or permissible interpretation of the statute. If the statute is determined unambiguous at step 1, the court will apply plain language statutory interpretation rather than proceed to step 2. *Id.* at 842-43.

past stance that it did not have authority to regulate tobacco products, and the broad framework of the FDCA, to conclude that the FDA lacked jurisdiction. The Court provided "[t]his is hardly an ordinary case" and that tobacco has "a unique place in American history and society" and "its own unique political history."[74] In essence, the Court utilized the "extraordinary"[75] history of tobacco rather than consulting the language of the FDCA to conclude that Congress had unambiguously spoken on the issue of whether the FDA had authority over tobacco products, and had resoundingly rejected jurisdiction through other means outside the FDCA itself.[76]

III. CONGRESSIONAL RESPONSE: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009

Congress eventually provided the FDA with the requisite jurisdiction and authority to regulate tobacco products. Nine years after Brown & Williamson, Congress amended the FDCA and the FCLAA by enacting the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA).[77] Signed into law by President Obama in July 2009, the TCA inserts a substantial new chapter codified within the FDCA, which grants the FDA sweeping oversight and enforcement authority over tobacco products, including cigarettes and smokeless tobacco.[78] Thus, the TCA supplements the FDCA statutory scheme rather than supplanting it.

The wide-ranging legislation creates a new Center for Tobacco Products (CTP) within the FDA,[79] requires manufacturers to register their

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[74] *Brown & Williamson*, 529 U.S at 159-60.

[75] Jack M. Beermann, End the Failed Chevron Experiment Now: How Chevron Has Failed and Why It Can and Should Be Overruled, 42 CONN. L. REV. 779, 821 (2010).

[76] For further analysis and discussion of the case, see Elizabeth Brown Alphin, Federal Tobacco Regulation: The Failure of FDA Jurisdiction Over Tobacco and the Possibility of Compromise Through a Congressional Scheme, 40 BRANDEIS L. J. 121 (2001); Joseph A. Fazioli, Chevron Up in Smoke?: Tobacco At the Crossroads of Administrative Law, 22 HARV. J.L. & PUB. POL'Y 1057 (1999); Marguerite M. Sullivan, Brown & Williamson v. FDA: Finding Congressional Intent Through Creative Statutory Interpretation—A Departure From Chevron, 94 NW. U. L. REV. 273 (1999); and Roseann B. Termini, The Legal Authority of the United States Food and Drug Administration To Regulate Tobacco: Calling on Congress, 74 ST. JOHN'S L. REV. 63 (2000).

[77] Pub. L. No. 111-31, 123 Stat. 1776 (codified in scattered sections of 5 U.S.C., 15 U.S.C. and 21 U.S.C. (2006)).

[78] *See infra* Part III.A & B.

[79] 21 U.S.C. § 387a(e) (2006).

products,[80] mandates adherence to manufacturing practice requirements,[81] requires disclosure to FDA of ingredients for all tobacco products,[82] grants the FDA authority to establish product standards,[83] permits the FDA to reduce nicotine (though not eliminate it) and other harmful ingredients,[84] bans misleading descriptors without substantiation,[85] enlarges tobacco product warning labels and requires graphic images on packaging,[86] and bans fruit and candy flavorings in cigarettes (although menthol is subject to further scientific study rather than an outright ban).[87] The FDA has since taken steps to implement the TCA, including issuing multiple guidance documents for industry.[88]

Several aspects of the TCA are particularly relevant to a discussion of e-cigarettes: the evident foundational concern from Congress regarding youth and adolescent tobacco use that emerges from the legislative history preamble; the scope of requirements for both new tobacco products and modified-risk tobacco products; and the statutory implications of the therapeutic claims made by manufacturers or distributors.

A. Congressional Goals and Legislative History

Congress was undeniably focused on protecting youth and adolescents from the powerful advertising and marketing force of the tobacco industry. The TCA enumerates 49 findings of Congress—21 of which specifically address the impact and effects of smoking and tobacco marketing on youth

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[80] *Id.* § 387e.

[81] *Id.* § 387e(e).

[82] *Id.* § 387d.

[83] *Id.* § 387g.

[84] *Id.* § 387g(d)(3).

[85] *Id.* § 387k.

[86] *Id.* § 1333.

[87] *Id.* § 387g.

[88] *See, e.g.*, CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORTING HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS AND TOBACCO SMOKE UNDER SECTION 904(A)(3) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2012) [hereinafter REPORTING HARMFUL CONSTITUENTS]; CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., REGISTRATION AND PRODUCT LISTING FOR OWNERS AND OPERATORS OF DOMESTIC TOBACCO PRODUCT ESTABLISHMENTS (2009) [hereinafter REGISTRATION AND PRODUCT LISTING].

and adolescents.[89] In fact, the second identified purpose of the TCA is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[90] The legislation expressly calls for the reintroduction of the 1996 FDA regulations struck down in *Brown & Williamson*,[91] which have since been codified in 21 CFR §1140. The FDA has also issued draft guidance to industry detailing the scope of the provisions contained within those regulations.[92]

B. Statutory Structure and FDA Implementation

Historically, the FDA has struggled with the definitional frameworks drafted by Congress; scientific and technological advancements and novel products present particular challenges to the jurisdictional boundaries created by the legislative definitions. This is an acute problem for FDA regulation of e-cigarettes, as detailed below.

1. Tobacco Products

A tobacco product is defined by the TCA as

> any product made or derived from tobacco that is intended for human consumption, including any component, part, accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).[93]

The statute further provides that the definition does not include an article that is a drug, a device, or a combination product, which are subject to the drug and medical device provisions.[94] Therefore, any product subject to drug or device classification cannot simultaneously be a tobacco

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[89] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § 2, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C. (2006)).

[90] *Id.* § 3(2).

[91] 21 U.S.C. § 387a-1 (2006).

[92] CTR. FOR TOBACCO PRODS., *supra* note 55.

[93] 21 U.S.C. § 201(rr)(1) (2006).

[94] *Id.* § 201(rr)(2). The statute also states "A tobacco product shall not be marketed in combination with any other article or product under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement)." *Id.* §201(rr)(4).

product.[95] The threshold question is whether a given e-cigarette product should be classified as a tobacco product or a drug, medical device, or drug-device combination product.[96]

The definitions and requirements for drugs and medical devices hinge specifically on the intended use of the product: is the product "intended to affect the structure or any function of the body of man or other animals" or "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"? If so, it is categorized as a drug and subject to the relevant statutory and regulatory provisions. Is the product an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent" that is "intended to affect the structure or any function of the body of man or other animals" or "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"? If so, it is categorized as a medical device and subject to the relevant statutory and regulatory provisions. If a product shares features of both, it is regulated as a drug-device combination by the FDA.

A key feature of the definition of tobacco product is the phrase "or derived from tobacco."[97] Clearly, cigarettes and cigars are made from tobacco because the products themselves contain tobacco in some form along with other ingredients. Smokeless tobacco, sold in the form of either snuff or chewing tobacco, likewise contains tobacco as the core ingredient.[98] Unlike traditional cigarettes and smokeless tobacco, e-cigarettes have become popular precisely because they are promoted as having a single key ingredient: nicotine. And nicotine is derived from tobacco. Based on a literal reading of the statute, e-cigarettes fall within the definition of tobacco product, despite the fact that they do not contain any tobacco.

Two other essential definitions create impediments for the FDA in the context of e-cigarettes. A "cigarette" is defined as a tobacco product that meets the definition of the term "cigarette" in the FCLAA and "includes tobacco, in any form, that is functional in the product, which, because of its

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[95] *Id.* §201(rr)(2).

[96] A combination product is a product having multiple mechanisms of action and is regulated according to the "primary mode of action." 21 C.F.R. § 3.2 (2011).

[97] 21 U.S.C. § 201(rr)(1) (2006).

[98] *Smokeless Tobacco Facts*, CDC, http://web.archive.org/web/20121105192631/http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm (last updated Aug. 4 2011) (accessed by searching for http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm in the Internet Archive index).

appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco."[99] The FCLAA defines a cigarette as

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).[100]

This limits cigarettes to products that actually contain tobacco. Thus, the term electronic cigarette is a misnomer—according to the TCA, it is not a cigarette.

Smokeless tobacco is "any product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity."[101] Thus, although e-cigarettes are smokeless in that the atomizer vaporizes the nicotine, they are not a smokeless tobacco product within the meaning of the statute. These three core definitions—tobacco product, cigarette, and smokeless tobacco—position e-cigarettes as tobacco products as a general matter, but remove them from the realm of either cigarettes or smokeless tobacco. This definitional positioning is significant, as many of the core provisions of the TCA apply only to cigarettes and smokeless tobacco.[102]

2. New and Modified Risk Products

There are also heightened requirements in the TCA for "new" and "modified risk" products. Essentially, any product falling into either category will require a premarket review prior to entering the market. A "new tobacco product" is defined as any tobacco product that was not commonly marketed in the United States as of February 15, 2007 or any modification of a tobacco product, including a change in design or any component, part, or constituent, where the portion modified was commercially marketed in the United States after February 15, 2007.[103] The

[99] 21 U.S.C. § 387(3) (2006).

[100] 15 U.S.C. § 1332(1) (2006).

[101] 21 U.S.C. § 387(18) (2006).

[102] *See generally* CTR. FOR TOBACCO PRODS., supra note 55.

[103] 21 U.S.C. § 387j(a)(1) (2006).

FDA has published a draft guidance that lists the types of evidence a manufacturer can produce to establish that a product was marketed prior to February 15, 2007, including copies of advertisements, catalog pages, promotional material, trade publications, bills of lading, and freight bills.[104] The statute also allows a showing of substantial equivalence to a product that was commercially marketed prior to the critical date,[105] though the FDA has not yet provided any guidance on how this is to be accomplished by the manufacturer. Congress borrowed the phrase and concept of substantial equivalence from the medical device provisions.[106]

A "modified risk tobacco product" is "any tobacco product that is sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[107] The FDA has further clarified the scope of "sale or distribut[ion]" by a guidance document providing that prohibited representations can be found on the label,[108] labeling,[109] or any advertising, can be implicit or explicit, and can be directed to consumers through any type of media.[110] Previously, such products were identified with descriptors such as light, low tar, or mild. The use of such descriptors or any representations that the tobacco product offers a reduced risk is prohibited unless manufacturers satisfy all scientific data and comparative study requirements set out by the FDA. [111] The FDA has actively begun to enforce these provisions.[112]

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[104] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH AND HUMAN SERVS., ESTABLISHING THAT A TOBACCO PRODUCT WAS COMMERCIALLY MARKETED IN THE UNITED STATES AS OF FEBRUARY 15, 2007, at 3 (2011) (noting that any and all materials produced as evidence must be dated).

[105] The definition of substantial equivalence is a tobacco product that "has the same characteristic as the predicate tobacco products" or "has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health." 21 U.S.C. § 387j(a)(3) (2006).

[106] *Id.* § 360c(i)(1)(A).

[107] *Id.* § 387k(b)(1).

[108] *Id.* § 321(l).

[109] *Id.* § 321(m).

[110] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., MODIFIED RISK TOBACCO PRODUCT APPLICATIONS 6 (2012).

[111] *Id.* The Institute of Medicine published a special report identifying appropriate scientific measures for modified risk tobacco products. Inst. of Med., Scientific Standards for Studies on Modified Risk Tobacco Products (2012).

[112] *See* CTR. FOR TOBACCO PRODS., *supra* note 110.

3. Therapeutic Claims

Any claim by a manufacturer or distributor that a tobacco product has a therapeutic effect, such as claims that a product is a smoking cessation product or nicotine addiction treatment, will prompt regulation under the drug and device frameworks. This requires rigorous premarket requirements, including clinical trials, detailed product information, and FDA review. Examples of FDA-approved drug and device smoking cessation products include pharmaceuticals (*e.g.,* Zyban and Chantix), nicotine lozenges, nicotine nasal sprays, nicotine inhalers, nicotine skin patches, and nicotine gums.[113]

Figure 1 depicts the relationship among these definitions in the form of a Tobacco Product Decision Tree. As an initial matter, any representations about the product that signal a drug or medical device intended use, or therapeutic claims, such as use in smoking cessation, reduction, or as a healthy alternative to smoking, will trigger the drug or medical device provisions.[114] If no such representations exist, the next determination is whether it is a "tobacco product." For tobacco products that entered the market after February 15, 2007, the failure to verify substantial equivalence triggers heightened premarket requirements.[115] Likewise, products marketed as modified risk are subject to premarket requirements as well,[116] including comparison studies to existing products and submission of chemical composition information.[117]

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[113] For information regarding FDA approved products, see *FDA 101: Smoking Cessation Products,* FDA (Dec. 2012), http://www.fda.gov/forconsumers/consumerupdates/ucm198176.htm.

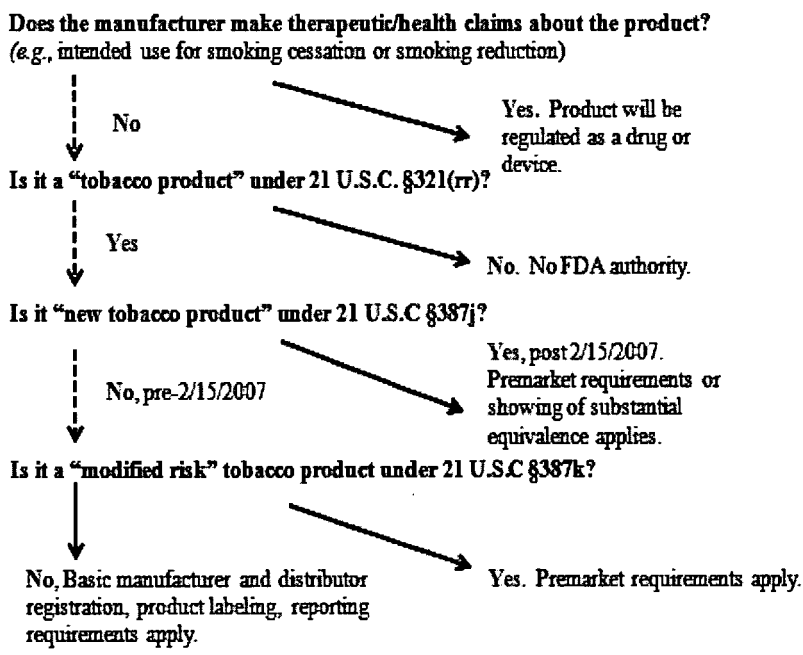
[114] 21 U.S.C. § 201(rr)(2)-(3) (2006).

[115] *Id.* § 387j(a)(1).

[116] *Id.* § 387k(b)(1).

[117] CTR. FOR TOBACCO PRODS., *supra* note 110, at 6.

Figure 1: Tobacco Product Decision Tree



4. Ban on Cigarette Additives

There is an explicit ban on flavoring additives for cigarettes,[118] a provision chiefly targeted to curb the appeal of cigarettes to youth:

[A] cigarette or any of its component parts...shall not contain, as a constituent...or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.[119]

[118] 21 U.S.C. § 387g(a)(1)(A) (2006).
[119] *Id.* § 387g(a)(1)(A).

The FDA has already carried out this ban, issuing warning letters notifying cigarette manufacturers and distributors that any product in violation would be subject to immediate enforcement action.[120] However, the scope of this ban and the regulations supporting it do not cover e-cigarettes because of the scope of the definition of "cigarette" contained in the TCA.

C. Industry-Launched Legal Challenges

Not surprisingly, the tobacco industry has lashed out against the FDA, filing lawsuits challenging provisions of the TCA as violating the First Amendment[121] and challenging FDA enforcement actions over e-cigarettes.[122] Litigation had been ongoing regarding the placement of graphic warnings on cigarette packaging and restrictions on various promotional activities.[123] However, Attorney General Eric Holder and the FDA are reportedly not pursuing an appeal to the Supreme Court.[124] FDA officials have stated they would "undertake research to support a new rulemaking consistent with the Tobacco Control Act."[125] As for e-cigarettes, a 2010 decision of the D.C. Circuit in *Sottera v. FDA* dealt squarely with questions about the definition of tobacco product as opposed to drug or medical device, the scientific and technical aspects of e-cigarettes, and the scope of intended use as it relates to therapeutic claims made by the manufacturer.[126] The *Sottera* case and its implications are discussed in detail in Part V.

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[120] Consumer information, press releases, transcripts of media briefings, and warning letters are available on the FDA's website. *See Flavored Tobacco*, FDA, http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/default.htm (last updated Mar. 21, 2013) (last visited Apr. 5, 2013).

[121] *See, e.g.*, R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266 (D.D.C.), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012); Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

[122] Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[123] *Overview: Cigarette Health Warnings*, FDA, http://www.fda.gov/TobaccoProducts/Labeling/ucm259214.htm (last updated Feb. 24, 2012).

[124] Michael Felberbaum, *U.S. Won't Appeal Ruling Blocking Graphic Cigarette Warnings*, AUGUSTA CHRON. (March 19, 2013), http://chronicle.augusta.com/news/business/2013-03-19/us-wont-appeal-ruling-blocking-graphic-cigarette-warnings.

[125] *Id.*

[126] *Sottera*, 627 F.3d 891.

IV. ELECTRONIC CIGARETTES GO VIRAL

The e-cigarette industry is booming—approximately 3.5 million Americans now regularly use e-cigarettes.[127] CDC studies show that e-cigarette use quadrupled in a single year from 2009 to 2010.[128] Based on 2011 numbers, 21% of adult smokers in the United States have used e-cigarettes, 6% of all adults have tried e-cigarettes, and general awareness of e-cigarettes rose to 60% of all adults, up from 40% in 2010.[129] The co-founder of the Tobacco Vapor Electronic Cigarette Association stated in March 2012 that nearly 20 million e-cigarette cartridges are sold in the United States. per week;[130] the chief financial officer of the Association recently estimated that the market will exceed $1 billion in U.S. sales by December 2014.[131]

A. From Atomizers to Vaping: A Product Overview

Popular media and public health literature alike attribute the invention of the e-cigarette to Hon Lik, a Chinese pharmacist, in early 2000.[132] Hon patented his invention first in the European Union[133] and then in the United States.[134] By the mid-2000s, the e-cigarette was marketed widely in China by the Ruyan Company and made its way to an international market by the

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[127] Mary Diduch, *North Jersey Companies See Growth Along with E-cigarette Industry*, RECORD (Jan. 18, 2013, 7:24 AM), http://www.northjersey.com/news/187414911_North_Jersey_companies_see_growth_along_with_e-cigarette_industry.html.

[128] John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, N.Y. TIMES (November 8, 2011), http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html.

[129] About One in Five Adult Cigarette Smokers Have Tried an Electronic Cigarette, CDC (February 28, 2013), http://www.cdc.gov/media/releases/2013/p0228_electronic_cigarettes.html.

[130] *E-Cigarettes Are Here to Stay*, CONVENIENCE STORE DECISIONS (Mar. 22, 2012, 11:21 AM), http://www.csdecisions.com/2012/03/22/e-cigarettes-are-here-to-stay.

[131] Diduch, *supra* note 127.

[132] Jonathan Foulds et al., *Electronic Cigarettes (E-Cigs): Views of Aficionados and Clinical/Public Health Perspectives*, 65 INT'L J. CLINICAL PRAC. 1037, 1037 (2011).

[133] Improved Atomizing Electronic Cigarette, European Patent No. 2,404,515 (filed Jan. 28, 2010) (issued Jan. 11, 2012); An Aerosol Electronic Cigarette, European Patent No. 1,736,065 (filed Mar. 18, 2005) (issued June 3, 2009); Flameless Electronic Atomizing Cigarette, European Patent No. 1,618,803 (filed Mar. 8, 2004) (issued Dec. 3, 2008).

[134] Electronic Atomization Cigarette, U.S. Patent No. 7,832,410 (filed Mar. 18, 2005).

year 2006.[135] Despite the renown of the Hon Lik invention, an examination of patent resources reveals numerous issued patents claiming smokeless delivery methods of nicotine, the earliest granted in 1965.[136] While these patents share various features and functions with the Ruyan e-cigarette and various similar products, they do not fully encompass the current mass-marketed form of the e-cigarette. The technology rapidly developed during the first decade of the 21st century.

The present day e-cigarette is a smokeless, battery-powered device that vaporizes liquid nicotine for delivery via inhalation by the user. The e-cigarette does not contain tobacco, only nicotine derived from the tobacco plant and trace amounts of several secondary chemical ingredients. It is composed of three parts that screw together: the nicotine cartridge; the atomizer (which vaporizes the nicotine); and the rechargeable battery that powers it.[137] Many products are also equipped with a light-emitting diode (LED) indicator at the end that is activated when the user draws in air. The cartridge contains liquid nicotine and is sealed either with an aluminum foil lid or with a plastic cork. A single cartridge can hold the nicotine equivalent of an entire pack of traditional cigarettes.[138] The composition, strengths,[139] and flavoring[140] of the nicotine liquid appear highly variable across different products.[141] Sottera doing business as NJOY, identifies the ingredients

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[135] Joan Lowy, *Ban Proposed on Electronic Cigarettes on Planes*, MSNBC (Sept. 14, 2011 3:25 PM), http://www.msnbc.msn.com/id/44518729/ns/travel-news/t/ban-proposed-electronic-cigarettes-planes.

[136] Smokeless Non-Tobacco Cigarette, U.S. Patent No. 3,200,819 (filed Apr. 17, 1963) (issued Aug. 17, 1965); *see also, e.g.*, Electronic Smoking System, U.S. Patent No. 5,934,289 (filed Oct. 20, 1997) (issued Aug. 10, 1999); Artificial Smoke Cigarette, U.S. Patent No. 7,845,359 (filed Mar. 22, 2007) (issued Dec. 7, 2010); Aerosol Electronic Cigarette, U.S. Patent No. 8,156,944 (filed May 15, 2007) (issued Apr. 17, 2012); Electronic Cigarette, U.S. Patent Application No. 10/886,508, (published Jan. 27, 2005).

[137] Legacy for Longer Healthier Lives, *supra* note 1.

[138] *See Smoking Everywhere E-Cigarette Cartridges 2.0*, SMOKING EVERYWHERE, http://www.smokingeverywhere.com/cartridges.php (last visited July 25, 2012) ("Each cartridge is equivalent to aprox [sic] 20 traditional cigarettes (100-200 puffs).").

[139] *Id.*

[140] *See Smoking Everywhere E-Cigarette Comes in Different Flavors*, SMOKING EVERYWHERE, http://www.smokingeverywhere.com/flavors.php (last visited July 25, 2012) (advertising flavors such as apple, cherry, strawberry, and chocolate).

[141] Letter from B.J. Westenberger, Deputy Dir., Div. of Pharmaceutical Analysis, FDA to Michael Levy, Supervisor Regulatory Counsel, Office of Compliance, Div. of New Drugs and Labeling Compliance, FDA (May 4, 2009), *available at* http://www.fda.gov/downloads/Drugs/ ScienceResearch/UCM173250.pdf [hereinafter Westenberger Memo].

(though not the concentrations) on its website as: propylene glycol, nicotine, ethanol, glycerol (glycerin), acetylpyrazine, guaiacol, myosmine, cotinine, and vanillin.[142]

The atomizer, which converts the nicotine liquid into a fine mist, consists of a metal wick and a heating element. When screwed onto the cartridge, the nicotine liquid from the cartridge comes in contact with the atomizer unit and is carried to the metal coil heating element. When one draws air inwards at the end of the e-cigarette cartridge, it triggers a current from the battery through the metal coil element in the atomizer which heats up the nicotine liquid.

B. An Industry Profile and Marketing Tactics

The vast share of companies distributing e-cigarettes and nicotine cartridges (also called "e-juice") market and sell their products utilizing both the internet and in-store purchasing. Notably, e-cigarettes have begun advertising on television, as the ban on television and radio cigarette commercials does not apply to them.[143] The cost of e-cigarettes range from about $20 to $150 for the starter kits; the replacement nicotine cartridges vary in price by retailer and location but seem to average about $12 for a 5 pack refill; and disposable e-cigarettes are now available for about $3 each.[144] While the typical e-cigarette is sold in the shape of a cigarette, many products are sold in the shape of discreet objects such as pipes,[145] pens,[146] and lipstick.[147]

Brands such as Smoking Everywhere,[148] NJOY,[149] and blu eCigs[150]

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[142] NJOY, *supra* note 10.

[143] "After January 1, 1971, it shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission." 15 U.S.C. § 1335 (Supp. 2011).

[144] These numbers were derived from online searches of e-cigarette websites, point-of sale advertisements, and pricing at retail outlets in March 2013.

[145] *E-CIG E-PIPE*, E-CIG.COM, http://www.e-cig.com/shopping/products/54-ecig-E-Pipe/ (last visited Apr. 5, 2013).

[146] *Pen Style e-Cigarette,* E-CIGS UNLIMITED, http://www.ecigsunlimited.com/kits/pen-style-e-cigarette (last visited Apr. 5, 2013).

[147] *Lipstick E Cigarette*, ALIBABA.COM, http://www.alibaba.com/product-gs/501751147/Lipstick_E_Cigarette.html (last visited Apr. 18, 2013).

[148] SMOKING EVERYWHERE, http://www.smokingeverywhere.com (last visited June 8, 2012). The website boasts: "Smoking Everywhere Electronic Cigarette looks like a traditional cigarette, feels like a traditional cigarette, tastes like a traditional cigarette, but it isn't a traditional cigarette. It's just a a [*sic*] tar-free way to enjoy smoking!"

have a prominent market presence. The industry is dominated by small, independent companies, with the exception of blu eCigs, which was acquired in April 2012 by Lorilland Tobacco Company for $135 million.[151]

Internet-based marketing of e-cigarettes commonly utilizes affiliate marketing schemes that enable users to distribute products and generate profits by recruitment of customers.[152] Some companies claim to have policies that require those seeking affiliate status to agree not to sell e-cigarettes to individuals under the age of 18 or to market the products as a smoking cessation product.[153] However, e-cigarettes are available for purchase from websites that do not verify age,[154] raising concerns about accessibility to minors. The strong internet presence of e-cigarettes can also be attributed to online communities of users[155] and frequent podcasts by sellers.[156] The tactics are working: Google has labeled "electronic cigarettes" as an online search term that has experienced a growth of over 5,000%.[157] Search trends are becoming a focus of study for researchers.[158]

Advertisements typically emphasize one or more of the following features of their e-cigarette products: freedom to smoke anywhere; no adverse smell, tar, smoke, or toxic chemicals; no social stigma; cost savings; and health advantages over traditional cigarettes, with several specifically reaching out to smokers aiming to quit or cut down.[159] Some companies and

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[149] NJOY, http://www.njoy.com (last visited Apr. 5, 2013).

[150] BLU ECIGS, http://www.blucigs.com (last visited Apr. 5, 2013).

[151] Diduch, *supra* note 127.

[152] *Id.*

[153] *See* Cyrus K. Yamin et al., *E-Cigarettes: A Rapidly Growing Internet Phenomenon*, 153 ANNALS INTERNAL MED. 607, 608 (2010).

[154] *See id.*

[155] *See, e.g.*, E- CIGARETTE FORUM, http://www.e-cigarette-forum.com/forum (last visited Apr. 5, 2013) (describing itself as the "world's largest electronic cigarette website").

[156] Yamin et al., *supra* note 153, at 607.

[157] *Id.*

[158] *See generally* John W. Ayers et al., *Tracking the Rise in Popularity of Electronic Nicotine Delivery Systems (Electronic Cigarettes) Using Search Query Surveillance*, 40 AM. J. PREVENTIVE MED. 448 (2011); Annice E. Kim et al., *Smokers' Beliefs and Attitudes About Purchasing Cigarettes on the Internet*, 121 PUB. HEALTH REP. 594 (2006); Annette K. Regan et al., *Electronic Nicotine* Delivery Systems: Adult Use and Awareness of the "E-Cigarette" in the USA, 22 Tobacco Control 19 (2013).

[159] The University Medical and Dental School of New Jersey (UMDNJ) has amassed an impressive collection of cigarette and tobacco advertising and marketing. UMDNJ, TRINKETS AND TRASH: ARTIFACTS OF THE TOBACCO EPIDEMIC, http://www.trinketsandtrash.org. Visitors to the website can search by category; selecting "e-cigarettes" will generate 40 results of e-

distributors advertise their products as not emitting secondhand smoke and as ecologically friendly.[160] The accuracy of these claims is unclear and hotly contested.[161] Premium Electronic Cigarette, which claims to be "one of the largest retailers of electronic cigarette systems and kits" states on its website that "[o]ne of the most important reasons why smokers are switching to electronic cigarettes is because they allow users to determine their nicotine intake, which is a great way to reduce their smoking habit without resorting to either quitting abruptly or to nicotine patches and gum."[162] American Blue Tip products are advertised as "a healthier, convenient alternative to cigarettes" and "so effective as a substitute for cigarettes."[163] It also directs consumers to "feed the hand to mouth habit."[164] In an ironic, almost inspiring twist, actor Stephen Dorff (for blu) tells consumers to "[r]ise from the ashes."[165]

Many celebrities have also touted the smoking cessation use of e-cigarettes publicly.[166] For example, in a 2010 interview with David Letterman, Katherine Heigl raved about her e-cigarette, stating that she had tried everything—the nicotine patch, gum, and prescription medication before turning to the e-cigarette.[167] She stressed to Letterman that her goal

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cigarette advertising from the past three years. These features of product claims were identified by the author using those 40 advertisements, television commercials, and direct email advertisements.

[160] Yamin et al., *supra* note 153, at 607.

[161] *Id.*

[162] PREMIUM VAPES, http://www.premiumecigarette.com (last visited Apr. 5, 2013).

[163] *See* Sch. of Pub. Health, *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, UNIV. OF MED. & DENTISTRY OF N.J., http://www.trinketsandtrash.org/detail.php?artifactid=7002 (last visited Apr. 5, 2013).

[164] *Id.*

[165] *See* Sch. of Pub. Health, *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, UNIV. OF MED. & DENTISTRY OF N.J., http://www.trinketsandtrash.org/detail.php?artifactid=7410 (last visited Apr. 5, 2013).

[166] *See, e.g.*, Celebrities Smoking Electronic Cigarettes: Leo DiCaprio, Katherine Heigl, JWoww Puff Away, HUFFINGTON POST (May 8, 2012, 4:46 PM), http://www.huffingtonpost.com/2012/05/08/celebrities-smoking-electronic-cigarettes-photos_n_1500814.html.

[167] CanadaVapes, *Katherine Heigl & David Letterman Vape Electronic Cigarettes*, YOUTUBE (Sept. 29, 2010) http://www.youtube.com/watch?v=ysGyfLwwr1s. One excerpt is particularly interesting:

> Katherine: "So I started to quit. . . . I tried everything; I did the patch, I did the gum, I did the Chantix, twice. . . . But now I do this. . . . Now I do the electronic cigarette."

was that she would eventually wean herself off of the e-cigarette entirely after utilizing it to quit smoking.[168] Charlie Sheen was named the face of a new e-cigarette called the NicoSheen in 2011.[169] OK! Magazine recently discussed Catherine Zeta-Jones being gifted Smokestik electronic cigarettes by a company representative to "support her quitting the bad habit."[170] A recently publicized celebrity endorsement for e-cigarettes came from Elliott Storm, a high profile disabled Vietnam veteran and author.[171]

Despite industry exhortations that e-cigarettes are not intended to be used in smoking cessation, public impressions reflect a majority of users who either rely on e-cigarettes to quit or reduce smoking, or who believe that e-cigarettes are a safer alternative to traditional cigarettes. Survey research indicates efforts to quit smoking were the most frequently cited reason for use of e-cigarettes.[172] The draw of the e-cigarette for smokers is that it delivers nicotine to counter nicotine withdrawal symptoms, it evokes the psychological response to cigarette smoking because of its shape, and it supports the familiar behavioral aspects of smoking.[173] The behavioral and physical stimuli alone (such as that associated with merely holding an unlit cigarette) are capable of reducing the craving to smoke.[174]

A number of studies have investigated public and user perceptions about e-cigarettes.[175] In a 2011 survey of 104 e-cigarette users, "[t]hree

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David: "and then you wean yourself off eventually and you'll be just fine."
Katherine: "Yeah that's the idea."

[168] *Id.*

[169] *Charlie Sheen Unveiled as the Face of New Electronic Cigarette*, DAILY MAIL (Apr. 30, 2011, 5:47 PM), http://www.dailymail.co.uk/tvshowbiz/article-1382270/Charlie-Sheen-unveiled-face-new-electronic-cigarette.html.

[170] Laura Lane, *Catherine Zeta-Jones Trying to Quit Smoking*, OK! MAGAZINE, (Aug. 5, 2011, 7:28 PM), http://www.okmagazine.com/news/catherine-zeta-jones-trying-quit-smoking.

[171] PRWeb, 21 Century Smoking Electronic Cigarette Company Gets Celebrity Endorsement, NEWSON6.COM, (July 2, 2012 10:07 AM), http://www.newson6.com/story/18931593/21-century-smoking-electronic-cigarette-company-gets-celebrity-endorsement.

[172] Yamin et al., *supra* note 153, at 607 (citing a study showing that 65% of respondents indicated that use of e-cigarettes was to quit smoking).

[173] Michael B. Siegel et al., *Electronic Cigarettes as a Smoking-Cessation Tool: Results from an Online Study*, 40 AM. J. PREVENTIVE MED. 472, 474 (2011).

[174] *Id.* at 472.

[175] *See, e.g.*, Ayers et al., *supra* note 158; Jean-François Etter, *Electronic Cigarettes: A Survey of Users*, 10 BMC PUB. HEALTH 231 (2010); Foulds et al., *supra* note 132; Regan et al., *supra* note 158.

quarters started using e-cigs with the intention of quitting smoking and almost all felt that the e-cig had helped them to succeed in quitting smoking."[176] One study reports that among 3,037 users of e-cigarettes, 77% of respondents said that they used them to quit smoking or to avoid relapse and 20% said that they used them to reduce consumption of tobacco with no intent to quit smoking.[177] In a larger survey involving 3,587 participants, over three quarters of respondents likewise stated
that one reason for their use of e-cigarettes was to quit smoking or avoid relapse.[178]

C. Public Perceptions, Public Health Perspectives, and a Dearth of Scientific Data

Several core concerns about e-cigarettes have been identified. The first concern is the uncertainty: the FDA and public health advocates seek conclusive studies as to the actual constituents of the products on the market in terms of nicotine levels, toxins, and other chemicals.[179] The FDA has directed extensive coverage to the risks of e-cigarettes, providing consumers with information on its website.[180] The second concern is the particular risk to youth: product flavorings such as grape, vanilla, and chocolate are being flagged as chiefly appealing to youth, encouraging them to use flavored e-cigarettes because popular flavorings in traditional cigarettes have now been banned.[181] The third concern is the misconception about the health benefits of e-cigarettes: claims made by manufacturers and distributors related to utility in smoking cessation or reduction in cigarette use, and statements

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[176] Foulds et al., *supra* note 132.

[177] *Id.* at 1040-41.

[178] Jean-François Etter & Chris Bullen, *Electronic Cigarette: Users Profile, Utilization, Satisfaction and Perceived Efficacy,* 106 ADDICTION 2017 (2011).

[179] *See, e.g.*, Bridget M. Kuehn, *FDA: Electronic Cigarettes May Be Risky*, 302 J. AM. MED. ASS'N 937, 937 (2009); *see also* Kuschner et al., *supra* note 22; Sungkyu Lee et al., *Public Health Challenges of Electronic Cigarettes in South Korea*, 44 J. PREVENTIVE MED. & PUB. HEALTH 235 (2011); Anna Trtchounian et al., *Conventional and Electronic Cigarettes (E-Cigarettes) Have Different Smoking Characteristics*, 12 NICOTINE & TOBACCO RESEARCH 905 (2010); Constantine I. Vardavas et al., *Short-Term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Acid*, 141 CHEST 1400 (2012).

[180] *Electronic Cigarettes (e-Cigarettes)*, FDA, http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm (last updated Oct. 9, 2012).

[181] Kuehn, *supra* note 179.

about the healthfulness of e-cigarettes are under close scrutiny.[182] The fourth concern is the risk of overconsumption: there is some attention directed to the lack of finality to an e-cigarette as being a potential problem, as smokers who have turned to the e-cigarette no longer have the butt of the cigarette as a cue to stop smoking. Unlike a traditional single cigarette that is typically smoked in its entirety and then discarded, use of an e-cigarette can be extended[183] in that a nicotine cartridge can contain up to twenty times the amount of nicotine of a single cigarette.[184] While a cigarette smoker has the ability to keep track of how many cigarettes in a pack he or she consumes, a nicotine cartridge has no such measure.

Little is known about the safety or adverse effects of e-cigarettes.[185] The popular medical information website, WebMD, recognizes the widespread use of e-cigarettes for smoking cessation purposes and urges clinical trials to determine safety.[186] Scientific and clinical publications have only begun to target issues related to e-cigarette use. An FDA study of two e-cigarette products revealed tobacco-associated chemicals, trace amounts of toxic chemicals, and varying levels of nicotine present in identically-labeled products.[187] Only one existing product, the Ruyan e-cigarette, has undergone

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[182] *See, e.g.*, Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL'Y 16 (2011); Pasquale Caponnetto et al., *Successful Smoking Cessation with Electronic Cigarettes in Smokers with a Documented History of Recurring Relapses: A Case Series*, 5 J. MED. CASE REP. 585 (2011); Riccardo Polosa et al., *Effect of An Electronic Nicotine Delivery Device (E-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study*, 11 BMC PUB. HEALTH 786 (2011); Siegel et al., *supra* note 173. In fact, the California Attorney General filed suit against Smoking Everywhere in early 2010 for misleading claims. Office of the Attorney Gen., *Brown Sues Electronic Cigarette Maker for Targeting Minors and Misleading Advertising Claims*, CAL. DEP'T JUSTICE (Jan. 13, 2010), http://oag.ca.gov/news/press-releases/brown-sues-electronic-cigarette-maker-targeting-minors-and-misleading.

[183] Respondents of one survey of e-cigarette users indicated an estimated median of twenty uses per day (where a single use was defined as 10-20 puffs). Foulds et al., *supra* note 132, at 1039.

[184] Electronic Cigarette Frequently Asked Questions (FAQ's), EPUFFER, http://www.epuffer. com/eshop/faqs-frequently-asked-questions.html (last visited Apr. 5, 2013). The website provides that "[o]ne regular cigarette would be equivalent to 10-15 epuffs," with the "Elite Classic" ePuff cartridge containing the nicotine of 18-20 cigarettes and the "Eaze [sic] Magnum" ePuff cartridge containing the nicotine of 20-25 cigarettes.

[185] Siegel et al., *supra* note 173, at 472.

[186] Daniel J. DeNoon, *Survey: E-Cigarettes May Help Smokers Quit*, WEBMD (Feb. 8, 2011), http://www.webmd.com/smoking-cessation/news/20110208/survey-e-cigarettes-may-help-smokers-quit.

[187] Kuehn, *supra* note 179.

a rigorous scientific study regarding safety using a risk-benefit methodology, though Ruyan funded the study.[188]

General questions about the overall safety of the products are being posited in light of several reports of death or serious injury resulting from e-cigarettes. In the United States, there have been at least two reports of e-cigarettes exploding in users' faces and hands causing severe injuries including blown out teeth, extensive burns and tissue damage to lips and tongue, burns to the hands, and hearing and vision loss.[189] Furthermore, a British doctor attributed the death of a patient from severe lipoid pneumonia, a lung disease, to e-cigarette use.[190] He posited (and continues to assert) that the inhalation of the oil in the e-cigarettes caused a similar result to those who are overexposed to oil inhalation over the course of their lifetime.[191]

V. FDA ACTION AND JUDICIAL REVIEW IN SOTTERA V. FDA

The FDA has begun testing the bounds of the statutory framework for regulation of tobacco products through enforcement actions against e-cigarette products. Although ultimately an unsuccessful attempt by the FDA to regulate e-cigarettes as drug-device products, the *Sottera* case is instructive in beginning to delineate the operative regulatory framework for the FDA as it faces a proliferating e-cigarette market.

A. Product Detention and Preliminary Injunction

The FDA has asserted its jurisdiction over e-cigarettes in two instances. In September 2008, the FDA detained several import shipments of e-

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[188] Murray Laugesen, *Second Safety Report on the Ruyan E-Cigarette*, HEALTH NEW ZEALAND LTD, (Apr. 9, 2008), http://www.mlm-infos.com/files/2ndsafetyreport_9apr08_930.pdf.

[189] Mikaela Conley, *Man Suffers Severe Injuries After E-Cigarette Explodes in His Mouth*, ABC NEWS (Feb. 15, 2012), http://abcnews.go.com/Health/electric-cigarette-explodes-fla-mans-face/story?id=15645605; *Electronic Cigarette Explodes in Muskogee Woman's Hand*, FOX23.COM (Apr. 18, 2012, 8:35 PM), http://www.fox23.com/mostpopular/story/Electronic-cigarette-explodes-in-Muskogee-womans/ek2x6P6rvkyLu5cMrvGwVQ.cspx; *Update: Was Exploding E-Cigarette a "Mod"?*, CSP DAILY NEWS (Feb. 20, 2012), http://www.cspnet.com/news/tobacco/articles/update-was-exploding-e-cigarette-mod.

[190] *Gateshead Doctor Calls for Research into "E-Cigarettes,"* BBC NEWS (Mar. 28, 2011, 4:27 PM), http://www.bbc.co.uk/news/uk-england-12887335.

[191] *Id.*

cigarettes manufactured by Smoking Everywhere, Inc. and subsequently issued notices of detention for violation of the FDCA.[192] A December 2008 correspondence establishes the asserted basis of jurisdiction: e-cigarettes and component parts are "intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction,"[193] thereby subjecting them to pre-market requirements under the FDCA as drug-device products. In March 2009, the FDA issued a refusal of admission notice and directed the detained products be exported or destroyed within 90 days.[194] In April 2009, the FDA also detained Sottera's shipment of e-cigarettes.[195] Smoking Everywhere and Sottera filed complaints on April 28, 2009 and May 15, 2009, respectively, seeking to enjoin the FDA from regulating e-cigarettes as drug-device combinations under the FDCA. The district court determined that the balance of harms favored Sottera and Smoking Everywhere and issued a preliminary injunction against the FDA.[196]

After detaining the imports, the FDA analyzed samples of the two products, including nicotine cartridges of various proclaimed amounts. Although the analysis was not a basis for the original detention of the products and not at issue in the case, the FDA has used the findings to support its position that e-cigarettes pose serious health risks. A May 2009 memorandum generated by the Deputy Director of the Division of Pharmaceutical Analysis within the Center for Drug Evaluation and Research at the FDA reported harmful volatile components in tests of both products, including tobacco-specific nitrosoamines and impurities, and even traces of diethylene glycol, a poisonous organic compound.[197] The tests also found that identically labeled cartridges contained varying amounts of nicotine.[198]

B. Appellate Review

On appeal to the D.C. Circuit, the court addressed whether the NJOY e-

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[192] Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 64 (D.D.C.), *aff'd sub nom.* Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[193] *Id.* at 65.

[194] *Id.*

[195] *Id.*

[196] *Id.* at 78-79. Smoking Everywhere did not continue as a party on appeal.

[197] Westenberger Memo, *supra* note 141.

[198] *Id.*

cigarette, marketed by Sottera, could be regulated as a drug or medical device or merely as a tobacco product.[199] Affirming the judgment of the lower court to grant a preliminary injunction against the FDA, the D.C. Circuit also held that the FDA's authority over the NJOY e-cigarette was limited to the provisions covering tobacco products.[200] Though the court noted a weak factual record on the marketing of e-cigarettes,[201] it found that without evidence that the company was making therapeutic claims, the "definitional line laid down in *Brown & Williamson* . . . leaves the FDA without jurisdiction over these products under the FDCA's drug/device provisions."[202]

The NJOY product itself was labeled for smoking pleasure rather than as a therapeutic or smoking cessation product,[203] which was critical to the court's decision. In reaching its conclusion, the majority read *Brown & Williamson* to exclude *all* tobacco products from the drug and device provisions (not just those products on the market at the time of the holding, *i.e.*, cigarettes and smokeless tobacco) as long as the manufacturer, NJOY, did not make drug-like claims.[204] The court determined that Congress had consciously developed a broader statutory scheme that distinguished customarily marketed tobacco products, including more than just cigarettes and chewing tobacco, from those tobacco products marketed for therapeutic purposes.[205]

C. Forgoing Further Appeal

The FDA ultimately decided to forgo appeal and issued a letter to the public setting forth its reasoning.[206] The letter assured adherence to the jurisdictional lines drawn by the *Sottera* court, while also indicating the relevance of other provisions of the statute that are implicated by e-

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[199] Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[200] *Id.* at 897. This authority includes restrictions on sale, advertising, manufacture, and the establishment of standards. *Id.* at 898.

[201] *Id.* at 898.

[202] *Id.*

[203] *Id.* at 893.

[204] *Id.*

[205] *Id.* at 897.

[206] Letter from Lawrence R. Deyton, Dir., Ctr. for Tobacco Products & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to stakeholders (Apr. 25, 2011), http://www.fda.gov/ newsevents/publichealthfocus/ucm252360.htm.

cigarettes.[207] For example, the FDA included requirements covering new tobacco products and a portion of the definition of tobacco product that includes those tobacco products marketed in combination with other FDA-regulated products.[208] The letter also emphasized that the FDA may issue a guidance document regarding therapeutic claims and triggers for regulation as a drug or medical device.[209]

The decision in *Sottera* and the FDA's subsequent decision not to appeal are woefully unsatisfying. The remainder of this Article is premised on two complementary positions. The first is that the TCA is inadequate for oversight of e-cigarettes, which are novel nicotine delivery devices for which the FDA ought to have the authority to assess safety and efficacy. E-cigarettes are not typical cigarettes consisting of tobacco grounds rolled in paper. Compared to a traditional tobacco product, e-cigarettes deliver a purer form of nicotine without the tobacco, the intake of nicotine is more rapid, and the user does not have the behavioral cue of a cigarette butt to signal the completion of a normal dose. Surely, the FDA safety assessment in the context of new drugs and devices deals with this phenomenon exactly, where novel delivery of excessive levels of active ingredients produce uncertain effects on the body.

The second position responds to the FDA's announcement that it will regulate e-cigarettes under the framework created by the TCA rather than pursue jurisdiction under the drug and medical device provisions. Going forward, the FDA will need to assess the industry as a whole to identify those claims, representations, and uses that do in fact trigger the drug-medical device requirements. This will require a prime focus not only on the explicit claims and representations of intended use of the product by both the original manufacturer and distributors, but also on implicit representations and actual consumer use.

VI. GOING FORWARD: STRENGTHENING REGULATION OF ELECTRONIC CIGARETTES

Absent a change in position from the FDA, e-cigarettes will be regulated under the framework espoused in *Sottera*. This Part informs the process of deciphering whether a manufacturer or distributor is making therapeutic claims or whether customary use implies an intended therapeutic

[207] *Id.*
[208] *Id.*
[209] *Id.*

use as a drug-device product. Despite the problematic analysis presented by the court in *Sottera*, particular claims, representations, and actual consumer use of e-cigarette products for smoking cessation or reduction do in fact trigger drug-medical device provisions. Even if the FDA takes the stance that actual consumer use fails to trigger drug-device provisions, various product features may trigger heightened requirements for new tobacco products and modified-risk tobacco products. The FDA may also rely on broad statutory authority from Congress to promulgate product-specific regulations and guidance.

A. Triggering Drug-Device Regulation Through Marketing, Promotion, and Consumer Use

Where the manufacturer of a tobacco product makes any claims or statements about the intended use of the product that fall within the drug or medical device definition, those statutory and regulatory provisions will apply. The FDA has clarified the scope of intended use by regulation:

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.[210]

This regulation makes clear that intended use extends beyond explicit claims and representations by the original manufacturer and the subsequent marketer. In fact, intended use includes representations by those affiliated with the product and actual consumers, if the distributor has knowledge of actual consumer use.

Claims made by the manufacturer on the product label and in marketing and promotion are the primary indicators of intended use. The FDA and Federal Trade Commission have made clear that company and manufacturer websites are also a source of promotional claims for purposes of enforcement. Increased monitoring and surveillance of manufacturer and distributor claims on labels and in advertising and promotion by the FDA and the CTP would assist in identifying problematic claims.

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[210] 21 C.F.R. § 201.128 (2011).

The FDA confronts challenges in several product realms by definitional lines demarcated by intended use.[211] For example, a cosmetic[212] is also regulated as a drug if claims are made that the product affects the structure or function of the human body or that the product will improve health or treat a health or disease-related condition.[213] The FDA has struggled with this line between a drug and a cosmetic for decades, as reflected by a litany of warning letters to industry[214] as well as informational materials on its website.[215] Even absent manufacturer claims, a cosmetic with a drug or drug-like intended use gleaned through customary consumer use or consumer perception may be regulated as a drug.[216] Unlike cosmetics, e-cigarette claims will not involve structure-function aspects, such as "lifting" wrinkles, "rebuilding" cells, or "repairing" imperfections.

With e-cigarettes, the challenge will likewise be policing the definitional lines. If a tobacco product manufacturer or distributor makes drug or medical device claims, it will be subject to the related requirements. For tobacco products, the traditional cigarette and smokeless tobacco manufacturers are careful to avoid marketing claims that sound therapeutic in nature, such as cessation or addiction treatment (triggering the drug requirements) or risk reduction (triggering the modified-risk requirements). The FDA will need to discern what claims made by e-cigarette manufacturers will similarly trigger heightened requirements. Given the novelty of e-cigarette technology (which means that the FDA is facing a rapid learning curve), coupled with aggressive marketing campaigns requiring vigilant watchdogging on the part of an already stressed administrative agency, manufacturers and distributors of e-cigarettes are currently thriving because of statutory and regulatory gaps and the

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[211] *See* Jordan Paradise & Ethan Fitzpatrick, Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?, 117 PENN ST. L. REV. 53 (2012).

[212] A cosmetic is another definition in the FDCA hinging on intended use, defined as "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance . . . ." 21 U.S.C. § 321(i) (Supp. 2011).

[213] *See id.* § 321(g)(1)(C). Foods and dietary supplements can make structure-function claims as long as they do not venture into unallowable health or disease-prevention claims.

[214] *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, FDA, http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm (last updated Nov. 26, 2012).

[215] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, FDA (July 8, 2002, updated Apr. 30, 2012),http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm [hereinafter *Is It a Cosmetic?*].

[216] *Id.*

inadequate enforcement. It will be years before the FDA can catch up with the claims targeted to consumers, though recent statements from the FDA indicate that this is a priority area following the outcome of *Sottera*.[217] Aside from direct representations made in marketing and promotion, any representation from the manufacturer or distributor in any public forum technically constitutes providing evidence of intent. Communications and reports to other administrative agencies within the federal government are readily available to the FDA to glean an intended use from representations contained within those sources. The FDA and other regulatory agencies often rely on these representations to support enforcement actions. For example, in framing a 1987 Regulatory Letter, the Department of Health and Human Services (DHHS) relied on the statements that Advanced Tobacco Products, Inc. made in labeling and promotional literature and in reports to the Securities and Exchange Commission (SEC) to support the finding that the FAVOR smokeless cigarette product[218] was a nicotine delivery system.[219] Accordingly, the letter stated that as a nicotine delivery system intended to affect the structure or function of the body through pharmacologic action, the FAVOR cigarette had violated the new drug provisions under the FDCA and its marketing should be discontinued.[220] The letter heavily referenced statements made by the company in its annual report to the SEC, including references to medical literature regarding the effects of nicotine on the nervous system and its addictive qualities.[221] The company responded with a letter indicating that distribution of the product had been curtailed pending preparation of a detailed response,[222] and the company ultimately removed the product from the market voluntarily without enforcement action by the DHHS. Given the voluntary withdrawal

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[217] Letter from Lawrence R. Deyton, *supra* note 206.

[218] Conceptually similar to present day e-cigarettes, when air is drawn through the tube over the nicotine solution, a small amount of nicotine is inhaled by the user. However, it contains no heating element or battery and operates simply by drawing air over the nicotine solution. U.S Patent No. 4,284,089 col. 3 ll. 25-30, (filed Apr. 2, 1980). The specific amount of nicotine inhaled during each draw of air is dictated by how constricted the passageway through the nicotine chamber is and by alteration of the surface area of the absorbent material. *Id.* col. 5 ll. 10-20.

[219] Regulatory Letter from Daniel L. Michels, Dir., DHHS, Office of Compliance, Ctr. for Drugs & Biologics (Feb. 9, 1987), http://www.legacy.library.ucsf.edu/documentStore/h/e/b/ heb65e00/Sheb65e00.pdf.

[220] *Id.* at 2.

[221] *Id.* at 1.

[222] Letter from James E. Turner, Chief Operating Officer, Advanced Tobacco Products, Inc. (Mar. 9, 1987) (on file with author).

of the product, reliance on these representations has not been tested in the courts.[223]

Patent filings with the U.S. Patent and Trademark Office or other international patent bodies are another useful resource. Any information provided to support a patent application and subsequent patent is made public and becomes part of the public domain, accessible to anyone via the internet. As a means to satisfy utility and novelty requirements in patent law, inventors support their invention description with reasons that their invention is useful and new for a particular application.[224] Patents for e-cigarettes may house a wealth of statements relevant to whether the manufacturer is representing the product as a smoking cessation or reduction product or is making claims of therapeutic benefit as compared to smoking risks.

For example, the inventor of the FAVOR smokeless cigarette described above was granted a patent in 1981 for a smokeless cigarette consisting of "a container defining a passageway therethrough and having a mouthpiece; means containing a source of vaporizable nicotine in fluid communication . . . [and] means for preventing the evaporation of said nicotine during periods of non-use . . . ."[225] The invention was "designed to reduce or eliminate the disadvantages associated with conventional smoking habits using combustible cigarettes"[226] and to "eliminate or ameliorate the adverse consequences" of smoking.[227]

The Lik Hon patent (assigned to Best Partners Worldwide Limited, reportedly acquired by Ruyan Investments) makes representations such as:

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[223] In the litigation leading up to *Sottera*, the FDA argued that the assertion of jurisdiction over the FAVOR smokeless cigarette is relevant for purposes of e-cigarette regulation. The district court noted that such an action was not judicially reviewed, it predated the Supreme Court's decision in *Brown & Williamson*, and it was "not in step with the reasoning of that case." Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 72 (D.D.C.), *aff'd sub nom.* Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010). However, the treatment of the FDA's assertion of jurisdiction over the FAVOR product is not satisfactorily discussed in the lower court decision, is relegated to a footnote, and is premised on a seemingly inaccurate framing of the reasoning of *Brown & Williamson*. Specifically, the district court states that the reasoning in *Brown & Williamson* was "based in part on FDA's representations to Congress that customarily-marketed tobacco products are not subject to FDA jurisdiction absent therapeutic claims." *Id.* Notably, the case does not address other aspects of the FAVOR history, namely the FDA's reliance on the SEC filings, to construe intended use of the product.

[224] *See* 35 U.S.C. §§ 101-102 (2006).

[225] U.S. Patent No. 4,284,089, *supra* note 217, at col. 14 ll. 52-59.

[226] *Id.* at col. 1 ll. 9-11.

[227] *Id.* at col. 2 ll. 4-5.

"only contain[ing] nicotine without the harmful tar;"[228] "provide[s] an electronic atomization cigarette that may function as a substitute for smoking cessation products or as a cigarette substitute;"[229] and "[the] advantages of the present invention include smoking without tar, significantly reducing the cancerogenic risk."[230] The patent also generally points out that "some cigarette substitutes" such as "nicotine patch, nicotine mouthwash, . . . nicotine chewing gum, nicotine drink" have a "major disadvantage"[231] and that the invention "overcome[s] the above-referenced drawbacks."[232] A Li Han patent (assigned to Ruyan Investments) provides that the invention "has been designed to provide an aerosol electronic cigarette that substitutes for cigarettes and helps the smokers to quit smoking."[233] The representations present within each of these patents strongly support a finding of an intended therapeutic use as a cessation or at least a modified risk product. However, it is unclear whether the FDA will succeed in using a patent claim as evidence of intended use for a particular e-cigarette product given complicated licensing arrangements that may exist between the inventor, patent assignee, and industry.

In tandem with increased general monitoring of marketing and promotion to mine for product claims, the FDA could search SEC filings and product-related patents in connection with manufacturer and distributor registration. The FDA could require submission of such materials at the time of registration, and on an annual basis through regulation or a guidance document.

B. Application of New and Modified Risk Provisions

Even where no drug or medical device claims are present, the FDA has at its disposal regulatory authority over the categories of new tobacco products and modified-risk products. Reports detailing the history of e-cigarettes identify a general presence in the U.S. market in the mid-2000s, with many sources pinpointing the exact date as some time in 2007. The FDA ought to determine when the various e-cigarette products entered the U.S. market and whether and to what extent changes in design are amenable to being grandfathered in as substantially equivalent to products already on

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[228] U.S. Patent No. 7,832,410, at [57] (filed Mar. 18, 2005).
[229] *Id.* at col. 1 ll. 53-55.
[230] *Id.* at col. 2 ll. 62-64.
[231] *Id.* at col. 1 ll. 35-41 (internal quotation marks omitted).
[232] *Id.* at col. 1 ll. 52.
[233] U.S. Patent No. 8,156,944 col. 1 ll. 58-60 (filed May. 15, 2007).

the market. The guidance to industry regarding new tobacco products is scant except to provide sources of evidence of market presence prior to the critical date.[234] Thus, elaboration on the role of substantial equivalence ought to be a priority for the FDA.

Future direction from the FDA on the new tobacco provisions will be important as the agency examines e-cigarettes and the timing of market entry for the various products and their progeny. The TCA appears to give the FDA the requisite authority to interpret the definition of substantial equivalence as applied to tobacco products. The FDA should consider interpreting the term strictly, not allowing incremental product changes without pre-market assessment. In the realm of devices, the FDA's inconsistent interpretation of substantial equivalence has raised significant safety concerns despite strong countervailing policy goals such as encouraging innovation and rapid introduction of new products.[235] Setting clear guidance is imperative.

Perhaps more useful for regulation and enforcement against e-cigarettes are the modified-risk products provisions contained in the TCA. Those products sold or distributed as reducing the harm or risk of disease associated with traditional cigarettes are subject to heightened requirements prior to marketing, including scientific data and comparative studies.[236] The FDA can use statements about risk reduction made in marketing, promotional materials, and SEC and patent filings to support regulation of e-cigarettes as modified risk tobacco products. Any label, marketing and promotional material, website, or other manufacturer representations about the product will likewise support heightened requirements. As noted in Part III, the FDA is also in the process of implementing these provisions of the TCA; guidance should focus on specific e-cigarette claims triggering heightened requirements.

C. E-Cigarette-Specific Regulations and Guidance for Standardization, Reporting, and Labeling

Alongside scrutiny of product claims, actual consumer use, and application of the new and modified-risk provisions, the FDA should also begin to gather information and impose standards on the e-cigarette industry. Additional efforts to regulate e-cigarettes should be directed

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[234] *See* Ctr. for Tobacco Prods., *supra* note 104.

[235] *See* Paradise, *supra* note 60, at 488.

[236] *See* 21 U.S.C. § 387k(b)(1) (2006); CTR. FOR TOBACCO PRODS., *supra* note 110.

toward the development of requirements to force uniformity and standardization across the industry, provide consumers with information regarding ingredients and nicotine levels, and create quality control mechanisms and product standards. This is not as daunting a task as it may seem.

The broad authority granted to the FDA, coupled with detailed statutory provisions, provides groundwork for the development of regulations and guidance regarding e-cigarette manufacturing and sale. Most relevant are provisions mandating manufacturer registration,[237] disclosure to the FDA of ingredients,[238] and manufacturing practice requirements.[239] The statute requires every owner or operator engaged in the manufacture, preparation, and processing of tobacco products to register the name, place of business, and a list of all tobacco products.[240] The statute also requires the FDA to promulgate regulations requiring testing and reporting of ingredients, constituents, and additives by brand and sub-brand requisite to protect the public health.[241] All ingredients, including tobacco substances, compounds, and additives, as well as a description of the milligram content, delivery, and form of nicotine in each tobacco product, must be reported.[242] Harmful and potentially harmful constituents (HPHCs) in tobacco products must be reported by brand and quantity;[243] the FDA has already developed a list of 93 HPHCs.[244] At a minimum, the FDA may require e-cigarette manufacturers and distributors to register and file a list of all tobacco products, ingredients, and HPHCs.[245]

The FDA has issued several nonbinding guidance documents for industry explaining the agency's current plans to interpret and develop the statutory requirements for filing and reporting.[246] The agency provides that as it moves forward with full implementation and enforcement of the

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[237] 21 U.S.C. § 387e (2006).

[238] *Id.* § 387d.

[239] *Id.* § 387e(e).

[240] *Id.* § 387e.

[241] *Id.* § 387o(a).

[242] *Id.* § 387d.

[243] *Id.* § 387d(a)(3).

[244] *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*, FDA (Mar. 2012), http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm.

[245] *See* REGISTRATION AND PRODUCT LISTING, *supra* note 88.

[246] *See id.*; Reporting Harmful Constituents, *supra* note 88.

reporting requirements via rulemaking it will revise or withdraw the guidelines accordingly.[247] While these guidance documents signal movement from the FDA, priority should be given to spell out these requirements to the e-cigarette industry and make it clear that the filing and reporting requirements apply to them.

Aside from the these actions covering filing and reporting, the FDA should require mandatory listing of all e-cigarette ingredients for labeling and packaging, similar to nutrition facts for foods[248] and supplement facts for dietary supplements.[249] The ingredients should be listed on each starter kit, nicotine cartridge, and disposable product in addition to all accompanying labeling and packaging for the product. The format and requirements for this information should issue through notice and comment rulemaking.

The TCA also grants the FDA authority to establish product standards.[250] Uniformity and standardization are also vital for the entire e-cigarette industry to assure consumer comprehension and industry accountability. This includes clearly conveyed nicotine levels for initial and refill nicotine cartridges; FDA-cleared design, mechanisms, and parts for the atomizer, battery, and nicotine cartridge; and, ideally, some notification to the user of the amount of nicotine consumed. This could possibly be built into the LED system as a changing color notification as more nicotine is consumed.

Quality control mechanisms are also necessary as part of manufacturing practices. The FDA has effectively implemented these in various other contexts, including food production[251] and drug[252] and device development.[253] These manufacturing practices would identify general constructs for personnel, grounds, facilities, equipment, processes, and controls, warehouse conditions, and distribution. The FDA would rely on these when investigating and inspecting a particular e-cigarette facility, and they would support enforcement action against violations.

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[247] Reporting Harmful Constituents, *supra* note 88, at 2.

[248] *See* 21 C.F.R. § 101.9 (2011).

[249] *Id.* § 101.36 (2011).

[250] 21 U.S.C. § 387g (2006).

[251] 21 C.F.R. § 110 (2011).

[252] *Id.* §§ 210-211.

[253] *Id.* § 820. This is called Quality System Regulation (QSR) in the device realm.

D. Congressional Additive Amendments

In order to address concerns about the allure of e-cigarettes to children under the age of 18, Congress should consider amending provisions in the TCA that ban additives in cigarettes by broadening their coverage to encompass e-cigarettes.[254] As written, the ban applies only to cigarettes, leaving e-cigarettes and various other products free to incorporate flavoring that may attract younger users. Likewise, legislation targeted toward e-cigarette marketing and advertising would also assist to curb the appeal and availability to adolescents and youth. However, the political will must exist to make such a change at the legislative level. Based on the nearly ten years it took Congress to enact the TCA, legislative fixes are not the primary or ideal means of enhancing regulation.

E. A Role for State and Local Authorities to Restrict Use and Sale

States and local governments can play a role as well, in parallel with FDA efforts to bolster regulation of e-cigarettes. A distinctive feature of the TCA is the broad latitude expressly preserved to state and local authority to regulate tobacco products.[255] Congress took pains not to limit authority of federal agencies, states, or Indian tribes to "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure" that "is in addition to, or more stringent than, requirements [under the TCA], including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco."[256] The preemption clause directly following the preservation clause does set bounds to this, in that federal requirements regarding product standards, pre-market review, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified-risk tobacco products preempt state and local requirements that are different from, or in addition to, the federal requirements.[257]

This preservation will be essential to the states and localities as the FDA rolls out regulations. It leaves much room for restrictions crafted more

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[254] 21 U.S.C. § 387g(a)(1)(A) (2006).

[255] 21 U.S.C. *Id.* § 387p(a)(1) (2006).

[256] *Id.* § 387p(a)(1).

[257] *Id.* § 387p(a)(2)(A).

specifically to the geographic location and local political environment.[258] State and local regulatory efforts will likely continue to focus on smoking bans and restrictions on promotional activities.[259] Proactively assessing and characterizing e-cigarette use, distribution, and promotion as part of state and local efforts would be a valuable step. Specifically, authorities should take care in drafting smoking bans to include e-cigarettes.

Thirty-nine states and 3,671 municipalities already have laws in place restricting or prohibiting smoking in public places and workplaces.[260] However, the laws were drafted with cigarettes and traditional tobacco products in mind. Many specifically use the word "smoke" or "smoking" to define the restricted or prohibited action. States must be careful to draft relevant laws to explicitly include e-cigarettes if the intent is to prohibit or restrict that action in addition to traditional means of smoking. For example, New Jersey has become the first state to amend its public smoking laws to include electronic cigarettes. The New Jersey Smoke-Free Air Act (amended in 2010) prohibits smoking in indoor public places, workplaces, and in buildings or grounds of any public or nonpublic elementary or secondary school.[261] It defines "smoking" as encompassing "the inhaling or exhaling of smoke or vapor from an electronic smoking device"[262] and defines "electronic smoking device" as "an electronic device that can be used to deliver nicotine or other substances to the person inhaling from the device, including, but not limited to, an electronic cigarette, cigar, cigarillo, or pipe."[263] Likewise, Somerset, Massachusetts; King County, Washington; Madison County, Kentucky; Suffolk County, New York; Cattaraugus County, New York; Savannah, Georgia; and San Francisco, California have passed ordinances explicitly including e-cigarettes within the scope of their

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[258] For a discussion of state and local oversight opportunities under the TCA, see Leslie Zellers & Ian McLaughlin, *State and Local Policy as a Tool to Complement and Supplement the FDA Law*, 2 HASTINGS SCI. & TECH. L.J. 117 (2010).

[259] *See, e.g., id.*

[260] *Overview List—How Many Smokefree Laws?*, AM. NONSMOKERS' RIGHTS FOUND., http://www.no-smoke.org/pdf/mediaordlist.pdf (last updated Apr. 5, 2013). For a discussion of state and local laws regarding smoking and their lack of application to electronic cigarettes, see Daniel F. Hardin, *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, 2011 U. ILL. J.L. TECH. & POL'Y 433.

[261] N.J. STAT. ANN. § 26:3D-58 (West 2011).

[262] N.J. STAT. ANN. § 26:3D-57 (West 2011).

[263] *Id.*

smoking bans.[264]

Various jurisdictions, both states and municipalities, have also enacted laws requiring licenses to sell e-cigarettes and banning sales to minors.[265] Others are under consideration.[266] States and local governments should assess their current smoking bans and other restrictions and decide whether to amend the language to include e-cigarettes. The political will and regional differences in views on smoking will drive these efforts.

CONCLUSION

The ever-rising hype and consumption of e-cigarettes is an opportunity to examine, interpret, and apply legislation governing tobacco products, as well as reassess the scope of drug and medical device regulation. The success of the e-cigarette industry signals the proliferation of a product containing a highly addictive chemical that currently evades regulation in light of recent case precedent and confusion regarding the scope of recently enacted legislation. If the public health is to be adequately protected, the FDA must initiate widespread investigations of product claims and representations made by the manufacturers that frame e-cigarettes as therapeutic products, as well as utilize the arsenal of statutory authority provided in the TCA. This Article, through historical exploration, comparative assessment, and statutory, regulatory, and case law interpretation and analysis argues that there is a feasible approach to strengthening regulation of e-cigarettes under the current statutory framework. This approach includes increased scrutiny of manufacturer and distributor claims for therapeutic intent triggering drug or medical device provisions, examination of actual consumer use of e-cigarette products, application of the new tobacco product and modified-risk tobacco product provisions, and additional regulatory movements from the FDA to foster uniformity and standardization, quality control, and access to product information.

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[264] Karen Blumenfeld, *Electronic Cigarettes (E-Cigarettes)*, GLOBAL ADVISORS ON SMOKEFREE POLICY (Feb. 1, 2013) 1-2, http://www.njgasp.org/E-Cigs_White_Paper.pdf.

[265] *Id.* New York recently enacted such a law, which also bans e-cigarettes use within 100 feet of a public or private school. Glenn Bain, *Gov. Cuomo Signs Two Laws to Protect Children from Nicotine Addiction; One of the Measures Bans the Sale of Electronic Cigarettes to Youth Under the Age of 18*, N.Y. DAILY NEWS (Sept. 5, 2012, 6:01 PM), http://www.nydailynews.com/new-york/gov-cuomo-signs-laws-protect-children-nicotine-addiction-measures-bans-sale-electronic-cigarettes-youth-age-18-article-1.1152718.

[266] *See, e.g., id.*

EPCRA: A Retrospective on the Environmental Right-to-Know Act

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ABSTRACT:

October 2011 marked the 25th Anniversary of the Emergency Planning and Community Right-to-Know Act (EPCRA), which was celebrated for its "significant role in protecting human health and the environment over the last quarter century by providing communities and emergency planners with valuable information on toxic chemical releases in their area."1 This Note aims to evaluate the effectiveness of three important provisions of the statute—the Toxics Release Inventory, the emergency planning mandate, and the citizen suit provision—through a case study of their implementation in Institute, West Virginia, the site of an industrial accident that prompted the enactment of EPCRA in 1986. This Note argues that although EPCRA made significant improvements to industry transparency in terms of its production and release of hazardous substances, there remain significant barriers concerning adequate resources, informational tools, and enforcement measures. These challenges must be addressed to ensure that citizens are provided with equitable opportunities to inform and ultimately protect their communities from health and environmental hazards. Through interviews with Institute residents and members of a local community advocacy group, along with analyses of the current informational tools available to the public under the statute, the Note will discuss specific challenges facing industrial communities, and offer a series of practical and legal solutions to increase the effectiveness of the statute, particularly in the most economically and politically vulnerable communities.

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1 Emergency Mgmt., 25 Years of EPCRA, U.S. Envt'l Protection Agency (EPA), http://www.epa.gov/oem/content/epcra/epcra25.htm (last updated Oct. 17, 2011).

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INTRODUCTION: OUT OF DISASTER, A NEW EMERGENCY PLANNING REGIME

On August 11, 1985, a Union Carbide chemical manufacturing facility released mass quantities of methylene chloride and aldicarb oxime in the town of Institute, West Virginia, injuring six plant workers and sending 135 residents to area hospitals.[2] The incident occurred less than one year after Union Carbide's sister plant in Bhopal, India leaked several tons of methyl isocyanate (MIC), killing more than 3,800 people, and causing an estimated 15,000-20,000 premature deaths from exposure over a twenty-year period.[3] In response to these two incidents,[4] public protests around industrial accountability, and the specter of a Bhopal-like disaster in the U.S., Congress passed the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA),[5] which aimed to "help communities plan for emergencies involving hazardous substances" by creating requirements for local emergency plans, and community right-to-know laws to ensure that residents are provided with information on chemicals produced and emitted from local facilities.[6]

EPCRA is unconventional in that its objective is not the classic "command and control" of environmental impacts that characterize many environmental statutes from the 1970s like the Clean Air Act and the Clean Water Act.[7] The Act has four main goals. It sets requirements for: (1) emergency planning at the state and local levels, (2) emergency emissions notifications, (3) reports on the storage and transportation of threshold quantities of hazardous chemicals; and (4) yearly reports of toxic releases of listed chemicals above threshold levels.[8] Beyond these requirements, industries have no express obligations under the statute to mitigate releases or to reduce risks to their employees and their surrounding

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2 See Robert Abrams & Douglas H. Ward, Prospects for Safer Communities: Emergency Response, Community Right To Know, and Prevention of Chemical Accidents, 14 HARV. ENVTL. L. REV. 135, 143 (1990).

3 Edward Broughton, *The Bhopal Disaster and its Aftermath: A Review*, 4 ENVTL. HEALTH 1, 2 (2005).

4 Office of Solid Waste & Emergency Response, *The Emergency Planning and Community Right-to-Know Act*, EPA (Sept. 2012), http://www.epa.gov/oem/docs/chem/epcra.pdf.

5 Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986, Pub. L. No. 99-499, 100 Stat. 1728 (codified at 42 U.S.C. § 11011-11050 (2006)).

6 Emergency Mgmt., *Emergency Planning and Community Right-to-Know Act Requirements*, EPA, http://www.epa.gov/oem/content/epcra (last updated Mar. 28, 2013).

7 Many environmental statutes (e.g., Clean Air Act and Clean Water Act) are characterized as "command and control," which means that regulated entities are required to comply with specific "ambient standards, source-specific emission limits, or technology requirements." Nat'l Ctr. for Envtl. Econ., *Economic Incentives for Pollution Control: Command and Control,* EPA, http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/EconomicIncentivesPollutionControl.html (search "Command and control" in NCEE Custom Search box) (last updated April 14, 2013). EPCRA imposes no such standards or controls on regulated industries, regardless of the level of reported emissions. It simply compels the disclosure of information on those emissions.

8 *See* 42 U.S.C. §§ 11001-11023 (2006).

communities.[9] Nevertheless, as detailed below, this "toothless" statute has been instrumental not only in improvements in industry transparency to its neighbors and the larger public. Also, and perhaps unexpectedly, in increased self-policing by many industries of their emissions, both to appease investment stakeholders and to prevent costly waste from inefficiencies at their facilities.[10]

It is now widely accepted that there is a fundamental link between public health risks and the condition of the physical environment. Genetic factors undoubtedly play a role in the development of chronic disease, but "70 to 90% of disease risks are probably due to differences in environments."[11] Environmental exposures to air and water toxics, occupational hazards, and behavioral patterns, such as dietary choices and stress levels, effectively alter the physiology of the body. This creates an "internal chemical environment" more or less conducive to the development of chronic diseases[12] such as heart disease, cancer, and lower respiratory diseases, the top three causes of death in Americans.[13] EPCRA yields information that can be critical in assessing the relationship between environmental health and public health. It also highlights the impact of environmental burdens, such as chemical production facilities, on the health and quality of life of the nation's fenceline communities, many of which are segregated along race and class lines and politically marginalized.

A 2008-2009 report by the President's Cancer Panel identified three key challenges to mitigating environmental cancer risks: "limited research on environmental influences on cancer; conflicting or inadequate exposure measurement, assessment, and classification; and ineffective regulation of environmental chemical and other hazardous exposures."[14] Considering these obstacles, EPCRA's industrial emissions data, particularly from the Toxics Release Inventory (TRI), can be an indispensable and invaluable resource in research on the linkages between toxics and exposures and risks of cancer and other chronic diseases.

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9 *Id.*

10 *See* JAMES T. HAMILTON, REGULATION THROUGH REVELATION: THE ORIGIN, POLITICS, AND IMPACTS OF THE TOXICS RELEASE INVENTORY PROGRAM 80 (2005) ("Citizen group and industry respondents often agreed on the overall impacts of TRI data use. More than half the respondents in each of the categories agreed that the release of the TRI led to source reduction efforts at reporting plants, media coverage of the toxic releases, and the prompting of industry-citizen meetings.").

11 Stephen M. Rappaport & Martyn T. Smith, *Environment and Disease Risks*, 330 SCIENCE 460 (1990).

12 *Id.*

13 Nat'l Ctr. for Health Statistics, *Leading Causes of Death*, CDC, http://www.cdc.gov/nchs/fastats/lcod.htm (last updated Jan. 11, 2013).

14 President's Cancer Panel, *Reducing Environmental Cancer Risk: What We Can Do Now*, U.S. DEP'T OF HEALTH & HUMAN SERVS., at i (April 2010), http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

Such data are also critical in identifying and analyzing disparities in levels of industrial emissions and their attendant exposures in communities characterized by non-white populations, low socioeconomic status, and political disenfranchisement. Indeed, the origins of the statute itself are rooted in the narrative of environmental injustices occurring disproportionately in low-income communities and communities of color. The Union Carbide disasters in Bhopal and Institute, and numerous instances of siting environmental disamenities in historically marginalized communities, such as the 1982 placement of a PBC-contaminated soil landfill in a majority African American community in Warren County, North Carolina,[15] spurred the development of the grassroots environmental justice movement in the 1980s.[16] This movement is concerned not only with distributional inequalities in environmental burdens and benefits, but also with enhancing the people's right to know about the potentially hazardous environmental exposures in their own backyards.[17] Environmental justice advocates, including members of what became People Concerned About MIC (PCMIC), an Institute-based environmental health advocacy group, were instrumental in EPCRA's passage in 1986, providing critical media coverage and Congressional testimony in Institute about their experiences with their industrial neighbors.[18]

Twenty-five years later, EPCRA's informational mandate is more salient than ever to the cause of environmental justice, as environmental and public health scholars continue to discover linkages between race, class, place, and environmental and health outcomes. Several studies have confirmed the fact that communities segregated by race and class are "disproportionately likely to live in

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15 *See* Renee Skelton & Vernice Miller, *The Environmental Justice Movement*, NATURAL RESOURCES DEF. COUNCIL, http://www.nrdc.org/ej/history/hej.asp (last updated Oct. 12, 2006).

16 *Id.*

17 Environmental justice, as defined by the EPA, is

> the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has this goal for all communities and persons across this Nation. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.

Environmental Justice, EPA, http://www.epa.gov/environmentaljustice/index.html (last updated Feb. 11, 2013).

18 *See, e.g.*, Abbey Zink, *A Decade Later Chemical Industry Still Answering Bhopal*, 10 ST. J. (Charleston, W. Va.), Dec. 1994, at 1. Because the Union Carbide plant in Institute was the only facility in the U.S. that produced MIC, the small town received a torrent of media attention from major print and television media outlets, as described in a 1985 documentary by John Gaventa and Juliet Merrifield. NO PROMISE FOR TOMORROW: COMMUNITIES RESPOND TO THE BHOPAL TRAGEDY (Highlander Center 1985).

environmentally hazardous neighborhoods."[19] Even apart from the impacts of such hazards on physical health outcomes, as discussed above, a 2005 study found an association between residential proximity to industrial activities and increased levels of psychological distress, connected to "perceptions of individual powerlessness and neighborhood disorder."[20] Another recently published study, on the relationship between black/white racial segregation and lung cancer mortality rates in the U.S., revealed that African Americans living in highly segregated communities had lung cancer mortality rates 10% higher than African Americans living in the least segregated communities, even after controlling for smoking behaviors and socioeconomic differences.[21] The authors of the study noted several possible explanations for these disparities, such as unequal access to health care services or differences in biological responses to smoking and other environmental elements, and they suggested a focus on the physical environment to help diminish these unequal outcomes.[22] As the study's lead author stated, "If you want to learn about someone's health, follow him home."[23]

But beyond the statute's utility for further important research on environmental and public health impacts of industrial activities, much of EPCRA's power derives from its role in facilitating proper emergency preparedness and industry accountability to impacted communities. By understanding the implications and risks associated with reported emissions, along with comparative outcomes among industries in different neighborhoods, citizens can be more effective at protecting themselves during industrial emergencies and advocating against industrial abuses, thus placing them on a more even playing field with their powerful industrial neighbors.

This Note will evaluate EPCRA's effectiveness for advancing citizen awareness and advocacy, emergency preparedness, and citizen enforcement of its informational mandate. It will focus on three key provisions of the statute: the Toxics Release Inventory (TRI), the Local Emergency Planning Committees (LEPCs), and the enforcement powers of the citizen suit provision. Additionally,

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19 Awori J. Hayanga et al., Residential Segregation and Lung Cancer Mortality in the United States, 148 JAMA SURGERY 37, 41 (2013).

20 Liam Downey & Marieke Van Willigen, Environmental Stressors: The Mental Health Impacts of Living Near Industrial Activity, 46 J. SOC. BEHAV. 289, 305 (2005).

21 Hayanga et al., *supra* note 19, at 40. By contrast, lung cancer mortality rates for white Americans living in highly segregated communities were 3% lower than white Americans living in the least segregated communities. *Id.* Lung cancer leads in rates of mortality among all forms of cancer, and African Americans have the highest lung cancer mortality rates of all racial demographics. *See id.* at 37.

22 *See id.* at 41.

23 Sabrina Tavernise, *Segregation Linked in Study With Lung Cancer Deaths*, N.Y. TIMES, Jan. 16, 2013, http://www.nytimes.com/2013/01/17/health/study-links-segregation-and-lung-cancer-deaths-in-blacks.html (quoting Awori Hayanga, M.D.).

interviews with members of the Institute advocacy organization PCMIC will provide context for the challenges of implementing EPCRA, particularly in under-resourced, politically disenfranchised communities.[24]

Part II will provide a brief history of the small, unincorporated, and predominantly African American town of Institute, its relationship with the former Union Carbide plant (now Bayer CropScience), and the recent litigation leading to elimination of MIC storage and production at Bayer. Next, Part III will provide a critique of the aforementioned provisions of EPCRA, as well as several recommendations for improving the transparency and effectiveness of the Act. First, the TRI, the statute's standout provision, has provided researchers, the media, and to a certain extent, citizens with unprecedented information about the types and quantities of chemicals produced and released into the environment by most industries in the nation. Improvements in personal technology, such as computers and smartphones, have spurred the development of powerful tools that translate TRI data in ways that have aided health and environment researchers in advancing their scholarship, and have the potential to provide citizens with more powerful, nuanced, and easily accessible information about facility emissions and their attendant health and environmental impacts. However, technological and educational barriers diminish their potential utility for many of the most impacted citizens, ultimately detracting from the central purpose of the statute—supporting the public's right to know about harmful emissions in their local environment. If EPCRA is to fulfill this purpose, the Environmental Protection Agency (EPA) must consider and accommodate these challenges in the future development of TRI tools. To this end, public facilities like local libraries, outfitted with the necessary technology (and analog forms of the same information) along with trained personnel, are essential to closing this access gap. Additionally, the EPA could better utilize existing forms of information, such as the highly readable and detailed chemical profiles included in the Material Safety Data Sheets (MSDS) mandated by the U.S. Occupational Safety and Health Administration (OSHA). This would allow citizens to better identify and understand the risks associated with chemicals produced in their communities.

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24 Interviews were conducted via email at various times and in Institute, W. Va., on October 7-9, 2011, with five members of PCMIC:

1) Sue Davis, native of Institute, original member of PCMIC;
2) Donna Willis, native of Institute, original member of PCMIC;
3) Maya Nye, native of St. Albans, W. Va. in the Kanawha Valley, member of PCMIC since the late 1990s;
4) Pamela Nixon, native of Charleston, W. Va. in the Kanawha Valley, original member of PCMIC and Environmental Advocate, West Virginia Department of Environmental Protection (WVDEP); and
5) Warne Ferguson: native of Institute, original member of PCMIC.

Second, EPCRA's crucial state and local emergency planning mandate is vastly under-resourced. The required Local Emergency Planning Committees (LEPCs) are staffed by volunteer citizens and safety professionals on top of their existing commitments. They must contribute many hours not only to developing effective emergency plans for large communities, but also to processing citizen requests for information pursuant to EPCRA's other provisions. LEPC duties have increased in the wake of 9/11 and Hurricanes Katrina and Rita, as they were required to incorporate contingency plans for natural disasters and terrorist attacks into their existing industrial emergency plans. Where resources do exist, they are generally sparse and allocated on a competitive basis. Unsurprisingly, these conditions result in many defunct or nearly defunct LEPCs across the country, further undermining the purpose of the statute. To create the proper safeguards against all hazards, as expressly intended in the statute, Congress must provide adequate, non-competitive financial and technical resources to LEPCs, and mandate cost sharing by state governments. Finally, it will be critical for citizens and governments to collaborate in the stringent enforcement of EPCRA's informational mandate, as effective emergency plans are contingent upon the availability of information on local industries.

Third, EPCRA's citizen suit provision, which expressly allows citizens to sue facilities on behalf of the government for non-compliance with the statute, has been effectively defunct since the Supreme Court's 1998 ruling in *Steel Co. v. Citizens for a Better Environment*,[25] which held that citizen-plaintiffs lack Constitutional standing to litigate wholly past violations of EPCRA. The ultimate impact of this decision is that citizens have no recourse to hold industries accountable for failing to file the required information on time. Information related to chemical hazards is most valuable when it is timely. Stripping citizens of their ability to punish companies that miss the deadlines leaves little incentive for industries to ever file on time. Without timely information, LEPCs cannot create informed emergency plans, citizens are hindered in their efforts to keep industries accountable for their emissions, and researchers' efforts to create new knowledge about industrial impacts on the environment and public health are severely thwarted. To restore integrity to EPCRA, Congress must amend the citizen suit provision to expressly allow suits for wholly past violations of the statute.

Finally, the Conclusion provides a brief summary of EPCRA's challenges and the main proposals for improvement. The central argument of this Note is normative: EPCRA is an invaluable resource for building knowledge about industry impacts and creating comprehensive emergency plans for all communities. It also has the potential to empower thousands of fenceline communities with information to hold neighboring industries accountable for

25 523 U.S. 83 (1998).

their impacts on citizen and environmental health. But to reach those ideals, it must be revised, and its implementation strategies must change. The EPA must develop informational tools that are both physically and interpretively accessible to those who are most impacted by industry practices. Congress must allocate direct, adequate, and non-competitive funding to LEPCs so that they can properly and comfortably fulfill their important purpose. And Congress must amend the citizen suit provision of the statute to allow citizens to hold industries accountable for failing to abide by the express information deadlines in the statute.

I. INSTITUTE, WEST VIRGINIA AND UNION CARBIDE: A BRIEF HISTORY

Located along the Kanawha River, approximately nine miles from the state capital of Charleston, Institute is an unincorporated community in the center of what is known as "Chemical Valley"[26] due to the more than 20 chemical manufacturing facilities surrounding the several towns located there.[27] By population metrics like the U.S. Census and county demographic records, it is effectively an invisible town, due to both its unincorporated status and its racial demographics.[28] Although Institute is only one of several other unincorporated towns in the area, it is the only majority African American town in the Kanawha Valley. By contrast, almost 90% of the Kanawha Valley identified as white in the 2010 Census.[29]

The African American community in the Kanawha Valley was established in the 1800s and quickly became known for its landownership.[30] Pursuant to the

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26 *See* Associated Press, *West Virginians Divided About Living in 'Chemical Valley,'* OTTAWA CITIZEN, Aug. 20, 1985, at D10.

27 ROBERT D. BULLARD, DUMPING IN DIXIE: RACE, CLASS, AND ENVIRONMENTAL QUALITY 51 (3d ed. 2000).

28 According to the Philadelphia Region Census Bureau, which collects West Virginia census data, Institute is not large enough to be designated as a Census Designated Place, and is thus counted as part of a larger geographic area in Kanawha County. Telephone Interview with Kevin Holmes, U.S. Census Bureau, Phila. Region (Apr. 23, 2013). The West Virginia Department of Health and Human Resources, which collects census data, was only able to provide one census tract for Institute (Tract 104), but stipulated that the area could encompass more than one tract. Telephone Interview with Tom Light, Programmer for Statistical Services, W. Va. Dep't of Health and Human Res. (Apr. 23, 2013). Kanawha County itself is 89.2% white, and 7.4% black. *State & County QuickFacts: Kanawha County, West Virginia*, U.S. CENSUS BUREAU, http://quickfacts.census.gov/qfd/states/54/54039.html (last updated Mar. 11, 2013). Institute, as affirmed by all of the PCMIC members, most of whom have lived in Institute since World War II or earlier, is approximately 90% black. *See also* BULLARD, *supra* note 27, at 51 ("Blacks compose over 90% of the community's population."). Although the other unincorporated communities in the area are not represented in the demographic data, they are majority white, and are thus adequately captured in the demographic profile of the area.

29 U.S. CENSUS BUREAU, *supra* note 28.

30 *See* BULLARD, *supra* note 27, at 51.

Second Morrill Act of 1890,[31] the community residents successfully petitioned the state legislature to site the West Virginia Colored Institute[32] near where they had already bought homes and formed neighborhoods.[33] The community was named Institute after the school.[34]

Siblings Sue Davis and Warne Ferguson are native residents of Institute, and belong to a prominent family of landowners and educators in the area.[35] The story of the land their uncle owned, which is where the Bayer plant is now located, is well documented. In 1930, he sold the land to the state to build the historic Wertz Field, the "first airport in the Charleston area to offer scheduled airline service."[36] After World War II began in 1939, the Wertz Field was used increasingly to train military pilots through the National Civilian Pilot Training Program, including a number of Tuskegee Airmen, who were students at West Virginia State College.[37] When the federal government purchased the property in order to build a rubber factory to support the war effort,[38] however, Davis and Ferguson's uncle sued, claiming a violation of a covenant ensuring the land would not be used for anything other than the Wertz Field. He was paid $27,000 to drop the claim.[39] "If my uncle knew then what his land is being used for now," Davis asserted, "he never would have sold."[40]

Union Carbide purchased the plant in 1947 and still operates a portion of it today, although ownership of the facility is now shared among several chemical firms, such as Praxair and Dow Chemical Company.[41] From its inception, the plant proved to be a source of fear and resentment to the Institute community, which was transforming from a thriving center of education and power for African Americans into a dangerous industrial town.[42]

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31 Ch. 841, 26 Stat. 417 (codified as amended at 7 U.S.C. § 322-328 (2006)).

32 The school was renamed West Virginia State College in 1929, and then West Virginia State University in 2004. *History and Traditions: Our History Runs Deep*, WEST VIRGINIA STATE UNIVERSITY, http://www.wvstateu.edu/About-WVSU/History-and-Traditions.aspx (last visited Apr. 15, 2013).

33 *See* BULLARD, *supra* note 28, at 51.

34 Interview with Sue Davis in Institute, W. Va. (Oct. 7, 2011).

35 *Id.*

36 Louis E. Keefer, *Wertz Field*, W. VA. ENCYCLOPEDIA, http://www.wvencyclopedia.org/articles/987 (last updated Nov. 12, 2010).

37 *Id.*; *see also* Interview with Sue Davis, *supra* note 34.

38 Keefer, *supra* note 36.

39 Interview with Sue Davis, *supra* note 34.

40 *Id.*

41 Interview with Pam Nixon in Institute, W. Va. (Oct. 7, 2011). Ms. Nixon also gave a PowerPoint presentation at the interview entitled "Institute: The Journey," chronicling the history of Union Carbide beginning in 1947. *See also*, *Who We Are: Institute*, BAYER CROPSCIENCE, http://www.bayercropscience.us/who-we-are/institute (last visited Apr. 15, 2013).

42 Another significant change in Institute came after the Supreme Court's decision in *Brown v. Board of Education*, 347 U.S. 483 (1954). West Virginia State University, then a majority black

> It's been hell. In 1954 was our first disaster. The skies from that plant lit up like the sun . . . it was completely orange as far as you could see in the Institute area. My sister was living by herself and I was in Charleston. I got as far away as Dunbar and could still see the orange. I went to her and we ran outta there. She got sick, and eventually died of emphysema.[43]

Although the community was deeply concerned with the chemical threat of the Union Carbide plant, efforts to organize and advocate for industry accountability did not fully emerge until the subsequent incidents in Bhopal and Institute.[44] Several community members, including Davis, Willis, and Ferguson, formed People Concerned About MIC (PCMIC) shortly after Bhopal, when they discovered that Union Carbide also stored MIC at the Institute plant.[45] Fears about industrial safety, health impacts of MIC and other chemicals, and the possibility of a Bhopal-like disaster spread through the country, particularly after the 1985 Union Carbide accident.[46] This gave strong credence to the emerging environmental justice movement, which identified inequalities in environmental burdens suffered by poor communities and communities of color.[47] The public outcry galvanized Congress, which sent a small delegation of representatives, including Senator Henry Waxman of California and Representative Bob Wise of West Virginia, to Institute to investigate.[48] Pamela Nixon, an Institute resident who got involved in PCMIC after Bhopal and lives in close proximity to the facility, witnessed firsthand Union Carbide's denial of any potential parallels between the facilities in Bhopal and Institute.

> [After Bhopal], Union Carbide was saying that nothing like that would happen in Institute. And when 135 people ended up going to the hospital [after the Institute leak], the plants ended up

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college, quickly integrated—although the town did not—and enrolled a majority of white students, who mostly commuted to the school by the 1980s. *See* BULLARD, *supra* note 27, at 51-52.

43 Interview with Warne Ferguson in Institute, W. Va. (Oct. 7, 2011).

44 Interview with Pam Nixon, *supra* note 41.

45 *Id.*

46 *See* Rebecca S. Weeks, *The Bumpy Road to Community Preparedness: The Emergency Planning and Community Right-to-Know Act*, 4 ENVTL. LAW. 827, 833 (1997-98) ("As a result of these accidents, in 1985 and 1986, Americans became increasingly concerned about the activities of the chemical factories next door. One newspaper described the general attitude as 'chemophobia.'").

47 Although communities had been advocating against disparate environmental impacts since the 1960s, the environmental justice movement began in 1982 with a protest against a landfill in Warren County, N.C. in which "more than 500 people were arrested, the first arrests in U.S. history over the siting of a landfill." Skelton & Miller, *supra* note 15.

48 Interview with Pam Nixon, *supra* note 41.

> saying, 'you can't compare that to Bhopal.' PCMIC had meetings every week to have them explain the releases to the public.[49]

Nixon, Davis, and several other PCMIC members participated in Congressional hearings on the incidents, providing their observations and demands for greater industry accountability for the health and safety of the communities surrounding their facilities.[50] EPCRA emerged in 1986 as a type of covenant between facilities and their communities for increased communication about the dangers posed by the chemicals produced and emitted, and for greater collaboration to make effective emergency plans.

Because EPCRA's provisions only govern public access to information and emergency planning, organizations like PCMIC cannot use the statute itself as an action-forcing tool for pollution prevention in the same way it could use other environmental statutes, such as the Clean Water Act or the Endangered Species Act.[51] What EPCRA can do—and arguably did do in Institute—is provide a means of keeping industry activities and performance standards in the public spotlight to force companies to consider self-regulation to maintain shareholder support, to build important community relations, and to reduce the costs of wasteful production.[52] Thus, despite continuous malfeasance by what is now Bayer CropScience, as documented by Nixon in her capacity at the West Virginia Department of Environmental Protection (WVDEP),[53] PCMIC was able to incite public scrutiny of the storage and emissions of MIC in the community.

The organization's efforts reached a critical crossroads on August 28, 2008, when an explosion at Bayer's Larvin pesticide unit killed two workers and released unknown quantities of toxic chemicals into the neighborhood, causing a fire that burned for more than four hours.[54] The residue treater that exploded was propelled into the air by a runaway chemical reaction, 70 feet away from the aboveground MIC storage tank.[55] Ferguson's wife, who was at home during the incident, developed breathing troubles a few days later and died within two

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49 *Id.*

50 *Id.*

51 Indeed, whereas the Clean Water Act and the Endangered Species Act govern actual environmental harm, EPCRA is simply an information mandate. One critique of the statute is that it does not offer a cause of action to actually reduce the emissions that ultimately cause emergencies, however egregious those reported emissions may be. *See* Abrams & Ward, *supra* note 2, at 136-38.

52 *See* HAMILTON, *supra* note 10, at 80.

53 Interview with Pam Nixon, *supra* note 41. Ms. Nixon discussed several permit violations of and enforcement actions against the plant from the 1980s to the present.

54 *See* U.S. Chemical Safety & Hazard Investigation Bd., Report No. 2008-08-I-WV, Pesticide Chemical Runaway Reaction Pressure Vessel Explosion: Bayer CropScience, LP, Institute, West Virginia, August 28, 2008, at 1 (2011) [hereinafter CSB Report].

55 *Id.* at 7.

months.[56] Similarly, a student at West Virginia State University, who was living in a dorm on the side of campus farthest from the plant, died of respiratory illness a few days after the explosion.[57]

In the spring of 2011, PCMIC members and other residents filed suit against Bayer to enjoin further storage or use of MIC at the plant.[58] The federal district court granted a preliminary injunction against MIC production[59] pending Bayer's implementation of recommendations made by the U.S. Chemical Safety Board (CSB), which determined that the explosion was caused by poor safety protocols, untrained operations personnel, and malfunctioning equipment.[60] Submitting to pressure from the public and threats of further investigations by the CSB and the EPA, Bayer decided to phase MIC out of its production processes in 2011.[61] For members of PCMIC, the victory was a bittersweet end to the lengthy, heavily resourced battle for accountability from Union Carbide and Bayer.

> [W]e were kind of sad we didn't get to beat them in court. But even though we weren't the ultimate reason they quit using MIC, we felt that we still made an impact by keeping the public informed about it.[62]

II. EPCRA IN INSTITUTE: HOW EFFECTIVE?

EPCRA has four central mandates: emergency planning at the state and local levels, emergency emissions notifications, public reporting of storage and transportation of hazardous chemicals by industrial facilities, and the maintenance of a toxics release inventory to inform the public about certain hazardous substances being released into communities.[63] As with most environmental statutes, Congress also added a citizen suit provision to EPCRA, allowing private causes of action for industry non-compliance with the informational mandates of the statute.[64]

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56 *See* Ferguson v. Bayer CropScience, L.P., No. 2:11-cv-00087, 2011 WL 4479008, at *1 (S.D. W. Va. Sept. 26, 2011).

57 *See* Lawrence Smith, *Lawsuit Links Student's Death to '08 Bayer Explosion*, W. VA. REC., Sept. 29, 2010, http://www.wvrecord.com/news/230046-lawsuit-links-students-death-to-08-bayer-explosion.

58 *See Ferguson*, 2011 WL 4479008, at *1.

59 *Id.*

60 *See* CSB REPORT, *supra* note 54, at 3.

61 See Jeff Johnson, Methyl Isocynate: Bayer Ends Use of Infamous Chemical at West Virginia Plant, CHEMICAL & ENGINEERING NEWS, Mar. 25, 2011, at 10.

62 Interview with Maya Nye in Institute, W. Va. (Oct. 9, 2011).

63 *See* EPCRA, 42 U.S.C. §§ 11001-11023 (2006).

64 *See id.* § 11046(a)(1).

Prior to EPCRA's passage in 1986, there was no federal mandate for emergency preparedness for industrial disasters.[65] States varied widely in their levels of planning. In New York, for instance, witnesses at public hearings in the wake of the Bhopal disaster "recounted responses [to previous incidents] that were dominated by confusion, fear, and lack of information."[66] Institute was supported by a local emergency committee for 34 years prior to the passage of EPCRA, but the Kanawha Valley Industrial Emergency Planning Council membership included only industrial groups and the West Virginia State Police[67] before the 1985 Union Carbide accident.

Similarly, public right-to-know laws mandating compulsory industry reporting of hazardous materials and toxic emissions were codified only at the state level prior to 1986, and as such, there were no federally mandated baseline standards for reporting and enforcement.[68] The birth of EPCRA thus heralded a significant power shift for regulators, public health experts, environmentalists, and concerned citizens, who were given unprecedented access to information that could be used to force corporate responsibility, make practical decisions about where to live, and evaluate wasteful chemical production processes.[69] The statute is commendable for using information technology to improve industrial transparency, but implementation faces many practical and political challenges. This is particularly true in communities like Institute, which are dominated politically and economically by large industries, and lack adequate public representation of their interests.

The following Sections use the example of EPCRA's implementation in Institute to offer a critique of three of the statute's most important provisions: the Toxics Release Inventory, local emergency planning, and citizen enforcement of the statute.

A. Toxics Release Inventory: An Equal Right to Know?

Perhaps the most celebrated of EPCRA's provisions is the Toxics Release Inventory (TRI). The first regulatory mandate requiring a "publicly accessible online computer system,"[70] TRI reports yearly emissions, transfers, and disposals

65 *See* Abrams & Ward, *supra* note 2, at 144.

66 *Id.* at 156.

67 *History*, KANAWHA PUTNAM EMERGENCY PLANNING COMMITTEE, https://www.kpepc.org/Home/Who-Are-We/History.aspx (last visited Apr. 15, 2013). Kanawha County had an emergency planning committee prior to EPCRA, which restructured to meet the federal requirements for Local Emergency Planning Committees (LEPCs) after the passage of the statute.

68 *See* Abrams & Ward, *supra* note 2, at 151-56.

69 *See* HAMILTON, *supra* note 10, at 248-49.

70 Gary D. Bass & Alair MacLean, *Enhancing the Public's Right-To-Know About Environmental Issues*, 4 VILL. ENVTL. L.J. 287, 288 (1993).

of over 650 hazardous chemicals from more than 20,000 U.S. facilities.[71] The 1990 Pollution Prevention Act expanded TRI reporting requirements to include information about how facilities manage chemicals in their waste and recycling processes.[72] Users of TRI data can determine the volume of yearly chemical emissions and the percentage released into each environmental medium (air, water, land), as well as pollution reduction efforts by individual facilities.[73] To maximize its effectiveness, however, the EPA must prioritize citizen access to both the raw data and the interpretive tools developed to assess the impacts of the emissions, and should incorporate existing data on public health, chemical characteristics, and community demographics to provide a comprehensive picture of industrial impacts and any resulting disparities.

Understanding the extent of pollution gives environmentalists, community advocates, and government agencies substantial leverage to negotiate higher emissions standards and to reduce negative environmental impacts. As early as 1993, five years after the release of the first TRI data, researchers and policymakers observed significant changes not only in the EPA's environmental agenda, but also in the relationship between the agency and citizen advocates.

> Experience with TRI has shown that public access assists EPA in achieving its mission of environmental protection in three distinct ways. First, the public becomes active in pursuing issues, such as pollution prevention, thus enriching the resource base of the agency. Second, public access helps EPA personnel pursue a more coordinated approach to enforcement and to understand what is occurring in other sections of the agency. Finally, public access improves data quality, thereby improving program enforcement.[74]

Emissions data reflect substantial yearly decreases in total facility emissions since the passage of the statute. In 1988, the base year chosen by the EPA for the program, approximately 20,000 facilities reported on-site emissions and transfers of more than 300 listed chemicals with an aggregate total of 6.2 billion pounds.[75] By 2011, 21,000 facilities reported releases and transfers of 650 listed chemicals, but the total only came to 4.1 billion pounds.[76]

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71 *TRI Program Fact Sheet*, EPA (2011), http://www.epa.gov/tri/triprogram/RY_2011_TRI_Factsheet.pdf.

72 What Is the Toxics Release Inventory Program?, EPA, http://www.epa.gov/tri/triprogram/whatis.htm (last updated Jan. 4, 2013).

73 *TRI Program Fact Sheet*, *supra* note 71.

74 Bass & MacLean, *supra note* 70, at 303.

75 *See* HAMILTON, *supra* note 10, at 59, 75-76.

76 *See TRI Program Fact Sheet*, *supra* note 71.

The caveat to such progress, however, is that these data raise many critical questions, particularly about reliability and whether the statute, as opposed to other incentives, has been a true impetus for these reductions. TRI data are self-reported by facilities, which use different mechanisms to measure releases, including engineering calculations and best judgment.[77] Actual reductions may be exaggerated or undervalued by changes in monitoring methodology, production processes, or reporting requirements.[78] Also, because there are many chemicals not covered under TRI, facilities can choose to replace reportable chemicals with those that are still unlisted, so as to avoid public scrutiny.[79]

Despite these challenges, TRI remains a critical tool for bolstering public awareness of and corporate accountability for environmental harm and public health risks. To increase the program's efficacy, it is imperative that communities obtain equitable access to new tools and information generated for clearer, more nuanced interpretations of the data.

TRI data are available to the public in diverse forms, from paper reports to extensive electronic spreadsheets, as well as online databases. The databases are designed to manipulate multiple forms of data, such as health and geographic information, to identify patterns and trends.[80] PCMIC uses the basic data to compare releases reported by Bayer CropScience with other records the facility must provide for permits under other statutes.[81] This information provides a backup measure to ensure the integrity of the facility's emissions reporting, and to show the "company's pattern and propensity towards repeat offenses."[82]

The raw emissions data do not, however, provide enough context. Informed public decision making requires information beyond these raw numbers, such as exposure levels and pathways, or the health and safety implications of the emissions levels. The EPA itself acknowledges the limitations of its data, cautioning TRI users that the information as presented is "inadequate to reach conclusions on health-related risks,"[83] and that individual chemicals "must be

77 *See* HAMILTON, *supra* note 10, at 60, 76. Hamilton highlights a study issued by the Natural Resources Defense Council, entitled *A Right to Know More*, that criticized the EPA for only subjecting a "small subset of chemicals" to reporting requirements. *Id.* at 78. The goal of such environmental groups was to provide the public with information on the health effects of reported toxics in order to put pressure on industries to "reduce the aggregate use of toxics." *Id.* The fact that all toxic chemicals are not subject to the reporting requirements deeply hampers those continued efforts.

78 *Id.* at 78.

79 *Id.* at 79.

80 *See generally TRI Information*, EPA, http://www.epa.gov/tri/tridata/index.html (last updated Oct. 9, 2012).

81 Email from Maya Nye to author (Feb. 29, 2012).

82 *Id.* For example, EPCRA data can be useful for tracking emissions violations of other command and control statutes, such as the Clean Air Act or the Clean Water Act.

83 *Factors to Consider When Using TRI Data*, EPA 4 (July 24, 2012), http://www.epa.gov/tri/triprogram/FactorsToConPDF.pdf.

evaluated along with the potential and actual exposures[,] . . . the chemical's fate in the environment and other factors before any statements can be made about potential risks associated with the chemical or a release."[84] This kind of information is particularly critical in Institute, where facility emissions are often strong enough to detect through sight and smell, and residents frequently become ill with various cancers or neurological disorders.[85]

To mitigate this lack of contextual information, the EPA has developed two major data applications: TRI Chemical Hazard Information Profiles (TRI-CHIP), which identifies the health impacts of individual chemicals,[86] and the Risk-Screening Environmental Indicators (RSEI) Model, which uses TRI data to generate trends and patterns of exposure to the toxins that may pose the greatest risks to the public.[87] However, these tools, while technically available to much of the public due to the increased availability of computers and the internet, ultimately lack usability by average citizens. The applications are not compatible with all computers because they may require particular internet browsers (e.g. Internet Explorer), specialized software (e.g. Microsoft Access), administration rights, or extensive computer memory.[88] Users also require some background expertise in health or data analysis to fully benefit from the information generated.[89]

The equity implications of these challenges are clear when one considers that many communities burdened by polluting facilities are also less likely to have the necessary equipment to access these databases, much less the resources to train citizens to properly interpret and use the data in their advocacy. For instance, although Institute is mixed-income and centered around a university, most of the individuals involved in pollution prevention advocacy are older, and many do not have ready access to computers.[90] Moreover, no local programs exist to train computer-equipped citizens on how to read the data and maximize their

84 *Id.*

85 Interview with Donna Willis in Institute, W. Va. (Oct. 7, 2011). *See also* Interview with Sue Davis, *supra* note 34 ("You could go down the streets and count the cancers and neurological diseases by house. There was one case where we had three aneurysms in one household.").

86 Toxics Release Inventory (TRI) Program, *TRI-Chemical Hazard Information Profiles*, EPA, http://www.epa.gov/tri/tri-chip/index.html (last updated Nov. 2, 2012).

87 *Risk-Screening Environmental Indicators (RSEI)*, EPA, http://www.epa.gov/oppt/rsei/ (last updated June 24, 2012).

88 TRI-CHIP for example, requires the user to obtain Microsoft Access to properly use the tool. *See TRI-Chemical Hazard Information Profiles*, *supra* note 86. RSEI requires administration rights, Internet Explorer, and a significant amount of memory to operate. *See Risk-Screening Environmental Indicators (RSEI)*, *supra* note 87.

89 *See* Richard Engler, *Risk-Screening Environmental Indicators (RSEI)*, EPA 9 (Feb. 13, 2008), http://www.ecos.org/files/3028_file_Engler_Presentation.ppt. Engler's 2008 presentation highlights the fact that RSEI is used primarily by government agencies, academics, and industries, all of whom typically have the resources required for appropriate RSEI training and physical access to the application itself.

90 Interview with Pam Nixon, *supra* note 41.

usefulness.[91] The EPA conducts biyearly national trainings for TRI data, but they are quite costly and "too time consuming for the average person."[92] And although self-tutelage is possible, as demonstrated by Nye and Davis, who learned to read the basic data with some assistance from Nixon,[93] it is ultimately unsustainable as a means of effectively informing the larger public and maximizing the benefits of the more contextualized data available in these complex databases and applications.

One promising TRI tool is an application called myRight-To-Know (myRTK), which is designed for use on the web as well as on web-enabled mobile phones.[94] No additional software is required to operate the program. Users simply enter a location, and the application displays all TRI-reporting facilities in the area on a Google map.[95] A pie chart shows the percentage of overall emissions released from the facility into each environmental medium, and there is a list of emissions volumes for the facility's reportable chemicals.[96] Each facility is ranked nationally according to its releases, and users can determine what percentage of the county's total emissions is generated by each facility in the area.[97] Data columns beside each chemical indicate whether it has been associated with cancer or other health effects, a colored graphic indicates the facility's quarterly compliance status for the last three years, and two final rows indicate the time of the facility's last full inspection and the number of formal enforcement actions brought against the facility within a five-year period.[98] Finally, the application links to a more detailed facility report, which offers more enforcement and compliance data from other EPA regulatory programs, eight-year TRI reported emissions, and demographic data on communities within a

91 *Id.*

92 *See* Email from Maya Nye, *supra* note 81. The regular registration fee for the TRI Training Conferences is typically around $300, not including travel expenses and lodging. Although travel scholarships are available to waive the registration fee, they are very limited in number. *See* Environmental Council of States & EPA TRI Program, *Annual TRI National Training Conference* (2009), *available at* http://www.docstoc.com/docs/125300375/2009-Annual-TRI-National-Training-Conference. While the TRI Training Conference lasts for approximately three days, it is unclear how much time would be required to master the more complex applications.

93 Email Interview with Maya Nye, *supra* note 81.

94 *See myRTK*, EPA, http://myrtk.epa.gov/info/info.jsp (last visited Apr. 15, 2013).

95 *Id.* Users must search for the facility under the "Search" tab of the application. Facilities are displayed on the "Map" and "List" tabs.

96 *Id.* To view the data for the individual facility, users must click on the desired facility from the "List" tab.

97 *Id.*

98 *Id.*

one-, three-, and five-mile radius of the facility.[99] The information is available in both English and Spanish.[100]

A search for Institute reveals two TRI-reporting facilities, along with five other facilities with permits for chemical discharges under other EPA programs.[101] Data for Bayer CropScience indicates that the majority of its emissions (548,787 pounds) are discharged into the water, and almost all of the rest (273,699 pounds) are released into the air.[102] Five out of twenty-one reported chemicals are associated with cancer, and all are linked with other unnamed health impacts.[103] In terms of annual chemical releases, Bayer is ranked 88th of 2,959 TRI-reporting chemical industries in the nation.[104] Of thirteen TRI facilities in Kanawha County, Bayer is responsible for 30% of the total TRI releases for the reporting year.[105] The facility's three-year environmental permit compliance status (October 2009-September 2012) is listed as unknown or unavailable; however, a link to further compliance data (i.e. EPA Enforcement & Compliance History Online (ECHO)) indicates several formal enforcement actions against the plant in the past five years by both state and federal agencies.[106] The ECHO report for Bayer CropScience currently lists no demographic information for the local population, but previous visits to the website in recent years listed the incorrect figure that African Americans comprised only 5.2% of the population within a one-mile radius of the plant.[107]

Health statistics collected by the Centers for Disease Control and Prevention (CDC) are available through a link in the census data, if provided, offering

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99 *Id.* The "Detailed Facility Report" can be found by clicking the "More Compliance Data" link at the bottom of the graphic facility report.

100 *Id.* The "Search" tab contains an option to switch to the Spanish-language version of myRTK.

101 *Id.*

102 *See Facility Report: Bayer CropScience LP*, EPA, http://myrtk.epa.gov/info/report.jsp? IDT=TRI&ID=25112RHNPLROUTE (last visited Apr. 15, 2013).

103 *Id.*

104 *Id.* The list is ranked highest to lowest emitters.

105 *Id.*

106 *Detailed Facility Report: Bayer CropScience Institute Plant*, EPA ENFORCEMENT & COMPLIANCE HISTORY ONLINE (ECHO), http://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID= 25112RHNPLROUTE (click "More Compliance Data" at bottom of page) (last visited Apr. 15, 2013).

107 *Id.* The author's last visit to the website prior to the deletion of this census data was April 2012. Similar data are available in the ECHO report for the Union Carbide facility, which is part of the same industrial complex. *See EJView*, EPA, http://oaspub.epa.gov/envjust/env_just_ejv.get_geom?report_type=html&census_type=bg2k&p_caller=self&coords=-81.796850,38.388216&feattype=point&radius=1.0 (last visited Apr. 15, 2013) (noting that African Americans make up 5.2% of the residential population within a one-mile radius). Users can view the health statistics by clicking on the "Health" tab on this page. The census data was likely flawed due to Institute's unincorporated status, and the fact that the U.S. Census data does not capture unincorporated towns. *See supra* note 28. The percentage of African Americans in the county is only 7.4%. U.S. CENSUS BUREAU, *supra* note 28.

figures on various disease rates in the county and state, but no indication of whether or how those figures correlate with exposure to toxic emissions.[108] The additional information provided by the National-Scale Air Toxics Assessment (NATA), however, does provide some risk estimates for cancer, neurological hazards and respiratory hazards. CDC statistics collected for Kanawha and Putnam Counties from 1988-92 indicate that death rates from heart disease ranged from 123.5 out of 100,000 people for white females to 302.5 for black males.[109] Similarly, death rates for all cancers ranged from 122.6 per 100,000 people for white females to 214.4 for black males.[110] Perhaps most startling, however, the 2005 NATA risk estimates for Kanawha County were in the 93rd percentile for cancer, in the 90th percentile for neurological hazard risk, and in the 88th percentile for respiratory hazard risk, all of which, with the exception of the neurological hazard risk, were significantly higher than the statewide risk estimates.[111]

Due in large part to its simplicity, myRTK is the most transparent and user-friendly of the TRI applications. For Institute residents, much of what it offers is concrete evidence that reinforces what many already know or suspect: that the Bayer CropScience facility emits a large amount of toxics into the air, that the facility has been a persistent violator of its permits, that the demographic data for the area is misunderstood or wholly inaccurate, and that rates of cancer and neurological disorders in their community are very high.[112] Any new insight to be gained from myRTK is limited by the TRI data: because toxic releases are only available in the aggregate, the data lack details on the rates of releases into the environment and the significance of releases relative to the toxicity of the chemicals,[113] all of which can help communities to establish relative levels of human exposure over time. Further, the CDC health data, while informative, are mostly dated from the 1990s and not contextualized in terms of the TRI chemicals,[114] which might give users a sense of the levels of exposure that are

108 *See EJView*, *supra* note 107. Users can view the health statistics by clicking on the "Health" tab on this page.

109 *Id.*

110 *Id.*

111 *Id.* The 2005 neurological hazard risk was in the 94th percentile for West Virginia.

112 Interview with Donna Willis, *supra* note 85. Over the course of the interview, Ms. Willis, who has lived in Institute for her entire life, attested to common knowledge of Bayer CropScience's permit violations, the communities' exposure to toxins, the skewed demographic data because of the town's unincorporated status, and the various health outcomes in the community, namely cancer and neurological disorders.

113 Bass & MacLean, *supra* note 70, at 302.

114 *See EJView*, *supra* note 108. The CDC data offer only general statistics about illnesses in the area, but do not give indications of how health data corresponds to the toxics release data.

associated with illness. The TRI data in the myRTK application is also undated, so users cannot know whether it is current.[115]

Ultimately, most citizens, particularly those unfamiliar with TRI, are likely to come away from such data with more questions than answers. Although other resources exist to fill some of the gaps, they are either unincorporated into the more user-friendly applications (e.g. myRTK) such that average users would not know to look for them, or they are made available upon written request to the LEPCs. For example, pursuant to the Material Safety Data Sheets section of EPCRA, facilities must submit information to State Emergency Response Commissions (SERCs) and Local Emergency Planning Committees (LEPCs) on all chemicals handled or manufactured subject to the Occupational Safety and Health Administration Act (OSHA), which requires reporting for a larger range of chemicals than TRI.[116] Each facility must prepare and submit profiles on each of the OSHA-regulated chemicals it manufactures or stores over a threshold volume. These profiles, called Material Data Safety Sheets (MSDS), contain information on the characteristics of each chemical, its known health hazards, and recommended safety precautions.[117] MSDS are available to the public by request to LEPCs or SERCs, although many are linked from the EPA's website.[118] Additionally, data derived from MSDS are incorporated into the more complex EPA databases, such as RSEI and TRI-CHIP, providing important contextual information about individual chemicals and their respective traits and impacts.[119] Nixon, who has received training on TRI data, reported that the MSDS are also the most user-friendly tools for the public, as they are simple and readable.[120]

Facilities must also submit to SERCs and LEPCs annual inventory information on all OSHA-regulated chemicals, including the average daily amount on-site, the maximum amount allowed at any time, and the location of each chemical.[121] This information is designed to assist LEPCs in identifying and prioritizing the existing hazards in their communities for the purpose of incorporating them into local emergency plans. However, facilities in many states have discretion to submit the information in two different forms. They may provide either Tier I information, which only contains aggregate chemical volumes by category of hazard, or Tier II information, which is more detailed

115 *See, e.g.*, *Facility Report: Bayer CropScience LP*, *supra* note 102.

116 EPCRA, 42 U.S.C. § 11021 (2006).

117 *See* Abrams & Ward, *supra* note 2, at 153.

118 *See* TRI Program, *TRI-Listed Chemicals*, EPA, http://www.epa.gov/tri/trichemicals/index.htm (last updated Feb. 19, 2013).

119 MSDS information is incorporated into TRI-CHIP and RSEI databases. *See* TRI, *supra* note 86; *RSEI*, *supra* note 87.

120 Interview with Pam Nixon, *supra* note 41.

121 42 U.S.C. § 11022.

and includes the individual names and locations of chemicals.[122] Although many states now require Tier II information, which is far more useful for community risk assessment and targeted emergency planning,[123] several states still permit facilities to opt for only Tier I disclosures. Further, because of concerns over homeland security, particularly after 9/11, states may restrict public access to such information to an as-needed basis.[124] In West Virginia, for example, Tier II information can only be released after a formal request to the relevant LEPC of the SERC pursuant to the Freedom of Information Act (FOIA), and with the written authorization of the Director of West Virginia Division of Homeland Security and Emergency Management/State Emergency Response Commission.[125] Information may be redacted if it is protected under the federal Protected Critical Infrastructure Information Program, or if it contains trade secrets, or the facility indicates that it wants to keep the location of its production site confidential.[126]

TRI's knowledge-based tools offered communities unprecedented access to the operations of the facilities surrounding them. This empowered community members to organize and advocate for decreased emissions or even the removal of the highly toxic chemicals that had subjected them to substantial health risks,

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122 *See* Abrams & Ward, *supra* note 2, at 155.

123 *Id.*

124 For a discussion of the tension between EPCRA's information provision and national security concerns, see Trang T. Tran, The Emergency Planning and Community Right-to-Know Act and National Security: Restricting Public Access to Location Information of Hazardous Chemicals, 8 ENVTL. LAW 369 (2001-2002). Tran argues that "Congress should amend EPCRA to (1) restrict public access to some information by excluding location information of hazardous chemicals from the publicly available documents and (2) allow federal preemption of state law in certain circumstances." *Id.* at 370; *see also* Katherine Chekouras, Balancing National Security with a Community's Right-to-Know: Maintaining Public Access to Environmental Information Through EPCRA's Non-Preemption Clause, 34 B.C. ENVTL. AFF. L. REV. 107, 109 (2007) (arguing that state right-to-know legislation, if not preempted by federal law, can "respect legitimate national security concerns, and . . . critically assess[] what information is publicly disclosed").

125 Telephone Interview with Melissa Buckley, Superfund Amendments and Reauthorization Act Title III Project Manager, W. Va. Div. of Homeland Sec. & Emergency Mgmt. (Apr. 23, 2013).

126 *Id*; *see also Tier II Instructions*, W. VA. DIV. HOMELAND SECURITY AND EMERGENCY MGMT. 5 http://www.dhsem.wv.gov/SERC/Documents/Tier%20II%20Instructions.pdf (last visited Apr. 15, 2013). Section 322 of EPCRA authorizes facilities to withhold information on a chemical's identity if it provides sufficient evidence that the chemical identity is a trade secret. Such information must still be provided to the EPA Administrator, but will be withheld from public disclosure. 42 U.S.C. § 11042(a)(2) (2006). Subsection (b) lists the requirements for trade secret status, including efforts to protect confidentiality and potential competitive harm from disclosure. *Id.* § 11042(b). Individuals hoping to challenge an alleged trade secret may initiate a review process. *See id.* § 11042(d). Trade secret protection is not absolute: certain health-related information may not be withheld from health professionals, *id.* § 11042(e), and information on the adverse health impacts of undisclosed chemical must be made available to the public on request, *id.* § 11042(h).

degraded the environment, and decreased the quality of their lives and the value of their properties.[127] Forced to finally confront their pollution, industries responded both to external pressures from activist communities and shareholders, and to internal pressures from industry leadership concerned with the high costs of wasteful production processes.[128] The disclosure mandate can thus boast benefits from many perspectives. In Institute, the implementation of TRI was instrumental in PCMIC's 25-year fight to eliminate MIC from the Bayer CropScience plant, providing critical data about the amounts released into the community and raising awareness about the prospects of a Bhopal-like disaster in America.[129]

After 25 years, TRI data are widely integrated into new informational tools, which combine data on public health, geography, and other pertinent metrics to provide a more detailed portrait of the risks posed by reported releases to communities and the environment.[130] In the quest for more detailed information, however, the EPA has created instruments that lack basic accessibility and usability by much of the public, particularly those living in the most economically and environmentally burdened communities. Considering that people living in unincorporated towns like Institute lack their own political representation, it is even more critical that easily accessible and usable tools be available to support community empowerment. MyRTK, which shows great promise as a standard, universally available tool for understanding and contextualizing TRI data, lowers the barrier of usability, but still requires access to an internet-enabled computer or smartphone.[131] Further, unlike the EPA's more complex applications, myRTK does not integrate data from other sources to properly contextualize the TRI releases in terms of toxicity and health risk.[132] Such disparities in information create the risk of further stratification between environmentally burdened and environmentally benefited communities, due to the relative inability of under-resourced environmentally burdened communities to access, process, and act on this information.

There are, however, viable solutions to these inequities. As a starting measure, LEPCs could compile MSDS for all state facilities and make them available in paper form at public spaces, such as local libraries, so that citizens do not have to make formal requests to access them.[133] LEPCs could also simply include a link on their websites to EPA's MSDS database for those with internet access. Additionally, following the example of the National Institute for

127 *See generally* HAMILTON, *supra* note 10, at 208-43.

128 *Id.*

129 *See* Email from Maya Nye, *supra* note 81.

130 *See TRI Information*, *supra* note 80.

131 *myRTK*, *supra* note 94.

132 *Id.*

133 According to Nye, the local libraries in Kanawha County did provide this resource, but cancelled it post-9/11. Email from Maya Nye to author (Jan. 22, 2013).

Chemical Studies in West Virginia, the EPA could provide assistance to SERCs, LEPCs, or environmental organizations to generate annual scorecards for each state,[134] ranking facilities according to their emissions, and incorporating practical information, such as threshold reporting levels and chemical profiles, as well as more nuanced information, such as exposure pathways and toxicity statistics. Such information could also be provided in both paper and electronic format, and made available at public libraries.

Finally, despite the EPA's public disclaimers about the limitations of the released information, specialized databases like TRI-CHIP and RSEI have demonstrated the extent to which TRI data may be compiled to provide a more nuanced view of the impacts of the regulated chemicals on human health and the environment. MyRTK should offer the same quality of information. The application should integrate data from the MSDS, such that citizens selecting chemicals emitted in their communities would receive detailed profiles on relevant characteristics, along with numerical thresholds of harmful exposure where available. The CDC data linked to myRTK should appear alongside this information so that citizens can readily assess the health risks of the individual toxics, as articulated by the MSDS reports, alongside the available CDC statistics for the relevant counties and states. All of this information should be regularly updated so the public has access to the most recent research about the chemicals that are relevant to their health.

It is virtually undisputed that TRI has garnered great improvements in local emergency planning and research on the environmental and health impacts of the covered chemicals. But EPCRA should not be, and arguably was not meant to be, limited to those gains. The community right to know is about accessibility, not only of raw data and information, but also of actual understanding of the implications of that information for the health and safety of community members and their environment.[135] To properly protect the interests of the public, particularly those who are disparately impacted by environmental burdens, information must be contextualized and tailored to provide the answers that people need to make critical decisions about their health and their lives.

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134 *See Examples of NICS Projects*, NAT'L INST. FOR CHEMICAL STUD., http://www.nicsinfo.org/examples.asp (last visited Apr. 15, 2013). NICS generated West Virginia Scorecards using TRI data from the state from the beginning of the TRI program in 1987 until the organization discontinued the project in 2003. *See also West Virginia Scorecard*, NAT'L INST. FOR CHEMICAL STUD., http://www.nicsinfo.org/scorecard.asp (last visited Apr. 15, 2013).

135 *See* Emergency Mgmt., *supra* note 6 ("The Community Right-to-Know provisions help increase the public's knowledge and access to information on chemicals at individual facilities, their uses, and releases into the environment. States and communities, working with facilities, can use the information to improve chemical safety and protect public health and the environment.").

B. Emergency Planning and Response: Is Institute Successful?

Pursuant to EPCRA, states must establish State Emergency Response Commissions, which are usually incorporated into existing emergency/disaster response departments.[136] In turn, SERCs appoint Local Emergency Planning Committees (LEPCs) to serve in designated emergency planning districts.[137] Membership to LEPCs must include a range of representatives, from elected officials to community groups and emergency response personnel.[138] LEPCs are primarily responsible for creating and distributing a local emergency plan and processing public requests for Tier II information on OSHA-regulated chemicals.[139] The role of LEPCs cannot be overstated. They are communities' first defense against hazards resulting from industrial activities, natural disasters, and domestic terrorist attacks. Yet, as illustrated below, their vast responsibilities are immensely under-supported by the state and federal governments, reducing community incentive to invest precious time and personal resources in an arduous task, particularly in areas where the probability of industrial disasters seems slim. To ensure that all communities are sufficiently protected in case of emergencies, Congress and the states must provide adequate and non-competitive financial and technical resources to support LEPCs. Additionally, as emphasized below, Congress must ensure that the EPA and citizens can stringently enforce the statute so that LEPCs will have the timely information required to properly carry out their planning mandate.

As noted, the Kanawha Putnam Emergency Planning Committee (KPEPC), coordinates emergency planning for Institute.[140] Approximately 125 citizens, community group representatives, facilities managers, emergency response personnel, and other professionals are currently members of the KPEPC, and new membership is available by application.[141]

By most measures, KPEPC reflects the successful implementation of EPCRA's emergency planning provision. Indeed, the capacity for emergency planning in Institute and the surrounding Kanawha Valley was not one of the major concerns expressed by the PCMIC organizers, although, as will be discussed below, they did express concern about execution. They felt confident

136 *See* EPCRA, 42 U.S.C. § 11001 (2006).

137 *Id.*

138 *Id.* § 11001(c) ("Each committee shall include, at a minimum, representatives from each of the following groups or organizations: elected State and local officials; law enforcement, civil defense, firefighting, first aid, health, local environmental, hospital, and transportation personnel; broadcast and print media; community groups; and owners and operators of facilities subject to the requirements of this subchapter.").

139 *Id.* § 11001(a).

140 *See Who We Are*, KANAWHA PUTNAM EMERGENCY PLANNING COMM. (KPEPC), http://www.kpepc.org/Home/Who-Are-We.aspx (last visited Apr. 16, 2013).

141 *Membership*, KPEPC, http://www.kpepc.org/Home/Members.aspx (last visited Apr. 16, 2013).

that KPEPC has an active and diversified membership, and works diligently to create viable emergency plans based upon the collective expertise of its members and the information received pursuant to the statute.[142]

An EPA-funded 1999 LEPC Survey established three criteria that characterized "compliant" LEPCs: (1) membership structure and procedures (e.g. chairperson, emergency coordinator, and information coordinator; holding regular meetings); (2) public communications about the availability of EPCRA information or other types of data, and responding to requests; and (3) fully developed or developing emergency response plans. These criteria were also used in the 2008 LEPC Survey as a means of assessing the LEPCs' activities.[143]

KPEPC meets all of these criteria. It has a 15-member board of directors, including three executive officers (Chair, Vice-Chair, Secretary-Treasurer),[144] and a 148-person membership, inclusive of the directors.[145] The board meets every month, and the general membership meets bimonthly.[146] The Community Outreach Committee is responsible for notifying the public of the availability of EPCRA-mandated data as well as any other important public information, and for processing requests for the information.[147] The all-hazard plan, which many LEPCs adopted after 9/11,[148] prepares communities for a wide range of emergencies, including natural disasters and acts of terrorism, and is regularly updated and available to the public on KPEPC's website.[149] Finally, the Drill

142 Email from Maya Nye, *supra* note 81; Email from Pam Nixon to author (Mar. 20, 2012).

143 Mark Starik et al., *1999 Nationwide LEPC Survey*, CTR. FOR ENVTL. POL'Y & SUSTAINABILITY MGMT., GEO. WASH. U. 10 (May 17, 2000) [hereinafter *1999 LEPC Survey*], www.epa.gov/oem/docs/chem/lepcsurv.pdf.

144 *Board of Directors*, KPEPC, http://www.kpepc.org/Home/Who-Are-We/Board-of-Directors.aspx (last visited (Apr. 16, 2013).

145 All 148 members are listed in the KPEPC Directory. *See Directory*, KPEPC, http://www.kpepc.org/Home/Members/Membership-Directory.aspx (last visited Apr. 16, 2013).

146 *See Board of Directors: Meeting Dates*, KPEPC, http://www.kpepc.org/Home/Who-Are-We/Board-of-Directors/Meeting-Dates.aspx (last visited Apr. 16, 2013) (listing monthly meeting dates for the Board); *General Membership*, KPEPC, http://www.kpepc.org/Home/Members/General-Membership.aspx (last visited Apr. 16, 2013) ("The general membership of the Kanawha Putnam Emergency Planning Committee meets bi-monthly.").

147 *Committees: Community Outreach*, KPEPC, http://www.kpepc.org/Home/Who-Are-We/Committees/Community_Outreach.aspx (last visited Apr. 16, 2013).

148 Office of Emergency Mgmt., *2008 Nationwide Survey of Local Emergency Planning Committees (LEPCs)*, EPA 13 (2008) [hereinafter *2008 LEPC Survey*] http://www.epa.gov/osweroe1/docs/chem/2008_lepcsurv.pdf ("Numerous LEPCs report that since 9/11, they take an all-hazards approach to planning and no longer solely focus on chemical emergency preparedness.").

149 *See Emergency Management: All Hazard Plan*, KPEPC, http://www.kpepc.org/Emergency-Management/Basic-Plan.aspx (last visited Apr. 16, 2013) (describing the Kanawha Putnam Emergency Management Plan).

Planning and Exercise Committee conducts drills of parts of the plan several times a year.[150]

Of the 2,357 known LEPCs that were contacted for the EPA's 2008 LEPC survey, only 939 responded, consistent with response rates from the 1999 survey.[151] Though the 2008 survey did not conduct the same statistical evaluation of LEPCs as the 1999 survey, most 2008 respondents would be considered compliant by the 1999 criteria.[152] For example, of 909 respondents, 79% reported meeting at least on a yearly basis,[153] with 38.7% meeting on a quarterly basis.[154] Of 895 respondents, only 5.8% did not have an emergency plan.[155] Of the respondents, 59% reported that they conduct outreach to notify the public about the availability of their emergency plans and the chemical hazard data; however, relatively few of them (23.6% of respondents) maintained websites to disseminate that information, which is largely distributed by newspapers (67% of respondents).[156] The vast majority of the survey respondents (81.2% of 863 respondents) had experienced one or more chemical accidents in their service area within the previous five years, with 32.3% having experienced six or more accidents.[157] This fact, combined with the fact that only 40% of known LEPCs responded to the survey,[158] suggests a positive relationship between active LEPCs and frequency of chemical accidents.

Unlike most of the LEPCs surveyed, KPEPC receives some direct funding from the West Virginia SERC, allocated from funds received from reporting facilities, as well as member businesses and agencies.[159] This is significant because LEPCs are largely an unfunded mandate; indeed, the West Virginia Division of Homeland Security and Emergency Management, where the SERC is administered, does not receive any federal funding to administer the LEPC program.[160] This leaves many LEPCs in constant competition for the few federal grants available for emergency planning, and reliant on alternate resources, such

150 Email from Pam Nixon, *supra* note 142.

151 *2008 LEPC Survey*, *supra* note 148, at 4.

152 *Compare id.* at 17-19 (listing 2008 statistics on LEPC structure, meetings, and emergency plans), *with supra* note 143 and accompanying text (noting compliance criteria in the 1999 LEPC Survey pertaining to LEPC structure, data availability, and emergency response plans).

153 *2008 LEPC Survey*, *supra* note 148, at 18.

154 *Id.* at 8.

155 *Id.* at 19.

156 *Id.* at 12.

157 *See id.* at 20 (percentages in text calculated based on these data tables).

158 *Id.* at 4.

159 Email from Pam Nixon, *supra* note 142. The West Virginia Department of Homeland Security and Emergency Management collects filing fees from facilities reporting Tier II data, which is required in the state. The fees are scaled depending upon the quantity of extremely hazardous substances stored at each facility. *See 2012 Oil and Gas Fee Worksheet*, W. VA. DIV. OF HOMELAND SECURITY & EMERGENCY MGMT. (last updated Dec. 2, 2011) http://www.dhsem.wv.gov/SERC/Pages/TIERIIREPORTING.aspx (link to worksheet at bottom of page).

160 *See* Telephone Interview with Melissa Buckley, *supra* note 125.

as in-kind donations from local entities.[161] Although much of the substantive work performed by KPEPC is done by its volunteer membership, the committee is able to employ part-time staff to perform essential logistical functions.[162]

The strength of the current organization is most likely a result of its long and robust history, which predates EPCRA by over thirty years and covers the numerous emergency releases that have occurred throughout the Kanawha Valley.[163] Indeed, the 2008 survey reveals a strong positive correlation between higher levels of activity in LEPCs and frequency of emergencies.[164] For example, the likelihood that surveyed LEPCs had met within the previous twelve months directly corresponded to increased accident history.[165] Further, and perhaps more interestingly, the EPA found that communities with more frequent emergencies had a "higher level of agreement that . . . LEPC[s] ha[ve] a positive impact on chemical safety in their communit[ies]."[166]

Despite these accomplishments, KPEPC still faces practical challenges with implementing its plan when emergencies do happen. During the 2008 explosion at Bayer CropScience, for example, there were failures in communication between the emergency responders coordinated through KPEPC's Emergency Management Plan and the emergency response team within the facility, creating confusion as to how to direct the public and protect the responders.[167] The Chemical Safety Board (CSB) attributed much of the confusion and missteps during the accident to Bayer's non-responsiveness and delayed safety measures during the emergency, though it also found a few significant flaws in the KPEPC Emergency Plan.[168] As a result, emergency responders and residents were placed at higher risk for toxic exposure. Both groups reported that they had been exposed during the emergency, and many reported poor health symptoms in the days after the incident. Among them were Davis and Willis, who have filed a nuisance suit against the company, and Ferguson, who sued unsuccessfully for the wrongful death of his wife, allegedly caused by the accident.[169]

Although KPEPC adopted necessary amendments to their Plan, as prescribed by the CSB, the outcome of the 2008 incident raises important issues about LEPCs' power within communities and the level of support available to them as they create policies and protocols to protect public health and safety. Nixon, who has been a member of KPEPC since the mid-1980s, pointed to three key

161 *2008 LEPC Survey*, *supra* note 148, at 24.

162 Email from Pam Nixon, *supra* note 142.

163 *See History*, *supra* note 67.

164 *See supra* notes 151-158 and accompanying text.

165 *See 2008 LEPC Survey*, *supra* note 148, at 5.

166 *Id.* at 10.

167 *See* CSB REPORT, *supra* note 54, at 78.

168 *See id.* at 82.

169 Ken Ward Jr., *Two Suits Target Bayer Institute Plant*, CHARLESTON GAZETTE (Oct. 12, 2011), http://wvgazette.com/News/201110121685.

problems that, if resolved, could substantially improve the KPEPC—lack of funding, the fact that much of the work is taken on by "emergency service personnel who are already busy," and the persistent communications issues that plague every emergency response. On this last point, however, she noted that she was unsure "how it can ever be resolved."[170]

Nixon's concerns were strongly reflected in the 2008 survey. Lack of funding was cited by the most respondents as the single greatest obstacle to the success of the LEPCs,[171] and in an open-ended question, many responded "that achieving good participation rates at meetings is difficult because LEPC members are volunteers and are often busy with their other jobs or familial commitments."[172] Respondents also mentioned that "dedicated membership is the greatest single factor contributing to the success of their LEPC[s]."[173] Additionally, 72.8% of the respondent LEPCs received no technical assistance from the Federal government.[174] Of the LEPCs that did receive such assistance, 77.9% stated that it "played a significant role in guiding their LEPC activities."[175]

In the aggregate, these challenges seem to reflect a lack of adequate power. That is, although Congress created these entities with the intent of reducing the costly outcomes of industrial accidents, it delegated major responsibilities to LEPCs with none of the real power to maximize their effectiveness.[176] In the wake of 9/11 and Hurricanes Katrina and Rita, there is even greater demand on LEPCs than contemplated in 1986. Many states now rely on these entities to implement all-hazards emergency plans, which go far beyond EPCRA's original chemical hazards mandate to include contingencies for terrorism and natural disasters.[177] Though many states do provide resources to LEPCs and federal grants are available,[178] it is clear that the current financing scheme is nonetheless detrimental to the fulfillment of the statute.

While states have an obligation and interest in emergency planning within their borders, the imposition of such a comprehensive federal regulatory scheme should not place the burden of funding solely on state coffers. The 2008 survey found that 35.9% of 868 respondents receive some form of direct funding. Of 312 responding LEPCs that receive direct funding, 54.2% obtain it through state

170 *See* Email from Pam Nixon, *supra* note 142.

171 *See 2008 LEPC Survey*, *supra* note 148, at 15 (noting that, of 852 respondents, 37.3% cited funding as the single greatest obstacle to their success, followed by low membership involvement (20.1%) and public apathy (12.9%)).

172 *Id.* at 8.

173 *Id.*

174 *Id.* at 14.

175 *Id.*

176 *Id.* at 24-25. The survey highlights the lack of federal financial and technical support to LEPCs, which undermines their success.

177 *See Emergency Management*, KPEPC, http://www.kpepc.org/Emergency-Management.aspx (last visited Apr. 16, 2013)

178 *See* Weeks, *supra* note 46, at 859-63.

fees collected from reporting facilities, while 39.7% of LEPCs receive direct funding from federal grants administered by agencies such as the Department of Transportation and the Federal Emergency Management Agency.[179]

In order to adequately provide for the unfunded and under-funded LEPCs and to finally fulfill the purpose of the statute, Congress must create a source of direct, non-competitive funding for all of its EPCRA mandates. The state-based approach of levying funds from reporting facilities could be a viable model for a federal funding program. The EPA could set reporting fees for facilities based on the toxicity levels of their chemicals, thus creating additional incentives for facilities to reduce storage levels of the most hazardous chemicals or to phase them out altogether. Whatever the approach, federal and state government should be equitable financiers of the statute.

The 2008 survey results do not explain why only a few LEPCs receive federal technical assistance, though the statistics are clear that such assistance is effective and has a positive impact on the operations of LEPCs.[180] As such, federal technical assistance, along with funding, should be made readily available to all LEPCs. Furthermore, equipping LEPCs with greater resources might create opportunities for them to support the community in new ways, such as providing local TRI training workshops for residents and community organizers and launching more intensive public outreach campaigns to promote the right to know.

Beyond these necessary resources, the success of the emergency planning mandate is contingent upon the diligent implementation of other parts of the statute, including TRI, emergency release notifications, and the citizen suit provision. Information mandates are the linchpin of emergency planning; without accurate data about the existence and extent of various risks in the community, LEPCs cannot adequately anticipate emergencies or plan for safe evacuations, shelter-in-place scenarios, or containment schemes, all of which are critical for disaster mitigation. As mentioned above, the more accessible this information is to the public, both physically and interpretively, the greater the chances that communities will become more engaged in the planning process and responsive to emergency drills and actual evacuations in the event of a real emergency.

Is Institute prepared for the next emergency? In a 2010 internal survey of KPEPC members, 43% said that the there was a "medium" probability that another industrial accident resulting in a chemical release would occur, while 40% ranked the probability as "high."[181] When asked what the likely

179 *See 2008 LEPC Survey*, *supra* note 148, at 24.

180 *See id.*

181 *KPEPC Hazard Vulnerability Survey*, KPEPC 47 (Jan. 5, 2011), http://www.kpepc.org/KPEPC/media/KPEPC/PDFS/KPEPC-Hazard-Vulnerability-Survey_2011.pdf. The survey intentionally left the classification of probability vague (no temporal periods or specific definitions

consequences of such an accident would be, 40% responded that it would substantially impact the health and safety of residents, and 28% predicted that it would be life-threatening.[182]

KPEPC has remained committed to improving its Emergency Plan and has incorporated many of the recommendations offered by the Chemical Safety Board since the 2008 accident, including improving communications processes with the local Metro 9-1-1 call center, requiring facilities to report incidents directly to KPEPC, developing an emergency email system for residents in affected areas, and creating a matrix of information to be disseminated to the public during the course of an emergency.[183] The Committee and Metro 9-1-1 also conducted a drill in Institute to practice these improvements.[184] When KPEPC members were asked they felt about their general preparedness for another incident, 49% responded that they felt "good" and 45% said that they felt "fair," and 6% felt "poor."[185]

C. Citizen Suits: What Does the Steel Co. *Decision Mean for EPCRA's Future?*

Congress delegated power to the public to enforce EPCRA through citizen suits.[186] Such provisions are found in almost all of the major environmental statutes, with the purpose of expanding and strengthening enforcement beyond the regulating agency.[187] The first citizen suit provision was included in the Clean Air Act of 1970[188] in response to Congress' disillusionment with the under-enforcement of the 1967 version of the Act.[189] Debates abounded over this new power, with concerns ranging from frivolous litigation and crowded dockets to overburdened agencies and underserved communities.[190] The result was a compromise, a provision that empowered citizens to take enforcement actions against non-compliant industries, but only insofar as necessary to protect the community and the environment.

Citizen suits allow persons to sue industries that are out of compliance with environmental statutes or to take action against the relevant enforcement agency,

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of low, medium, high probability) in order to "allow participants to bring their own experiences to the assessment." *Id.* at 4.

182 *Id.* at 47.

183 *See* CSB REPORT, *supra* note 54, at 85-87.

184 *Id.*

185 *See KPEPC Hazard Vulnerability Survey*, *supra* note 181, at 47.

186 EPCRA, 42 U.S.C. § 11046(a)(1) (2006).

187 *See* Karl S. Coplan, *Citizen Suits*, *in* ENVIRONMENTAL LITIGATION: LAW AND STRATEGY 321, 323 (Cary R. Perlman ed., 2009).

188 42 U.S.C. § 7604 (2006).

189 *See* Coplan, *supra* note 187, at 321.

190 *See* Jeffrey G. Miller, Citizen Suits: Private Enforcement of Federal Pollution Control Laws 3-5 (1987).

usually the EPA, for non-enforcement of the statute.[191] To protect against frivolous suits and financial exploitation of the provision, citizen-plaintiffs cannot collect damages, though they may recover attorneys' fees and other costs of litigation if they prevail in court.[192] Civil penalties, which may be charged per day for each violation, remit to the U.S. Treasury, where they may be, but are not necessarily, used to fund environmental initiatives.[193] These suits are now substantial advocacy tools for individuals and environmental organizations, allowing them to represent and defend the environment and public health of communities that might otherwise slip through the overburdened federal enforcement scheme.[194] With a more direct means of achieving justice, citizens have greater incentives to be active monitors of their industrial neighbors, thereby expanding the nation's capacity for effective environmental enforcement.

The past 20 years, however, have seen a substantial reduction of these citizen enforcement powers through a series of cases interpreting citizen suit provisions of the Clean Water Act (CWA),[195] Resource Conservation and Recovery Act (RCRA),[196] and EPCRA. Most significantly, the 1998 Supreme Court decision in *Steel Co. v. Citizens for a Better Environment*[197] stated that citizen-plaintiffs lack Constitutional standing to litigate wholly past violations of EPCRA.[198] This decision has effectively abolished citizen claims under EPCRA, as it offers facilities a free pass to shirk reporting deadlines, so long as they submit the required information in the sixty-day statutory waiting period before citizens are allowed to file lawsuits. Under this enforcement scheme, citizens have little incentive to invest in suits that are highly unlikely to hold industries financially accountable for the untimely filing of mandated information. Stripping citizens of this enforcement power further diminishes industry incentive to file timely information under EPCRA, which undermines the integrity and effectiveness not only of the information provisions, but also of the emergency planning requirements which depend on these data. To remedy this problem, Congress should either revise the citizen suit provision of EPCRA to expressly allow citizen-plaintiffs to litigate wholly past violations, as it has done partially under the Clean Air Act (discussed below), or allow citizen-plaintiffs to recover civil penalties. Without such a revision, citizen enforcement of EPCRA will remain defunct.

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191 *See* Coplan, *supra* note 187, at 321-22.
192 *See id.*
193 *Id.*
194 *See* MILLER, *supra* note 190, at 3.
195 33 U.S.C. § 1365 (2006).
196 42 U.S.C. § 6972 (2006).
197 523 U.S. 83 (1998).
198 *Id.* at 109.

The Supreme Court's decision in *Steel Co.* was intended to resolve a split in the Sixth and Seventh Circuits over whether citizens could litigate wholly past violations under EPCRA's citizen suit provision. At the center of this split was a clause that is located in all environmental citizen suit provisions, requiring citizen-plaintiffs to 1) notify violators of the nature of their violation and the plaintiffs' intent to sue; 2) notify the State in which the violation occurred; and notify the EPA Administrator.[199] Plaintiffs must then wait sixty days from submitting the notification to file the suit. A violation becomes "wholly past" when it is resolved within the sixty-day period prior to the commencement of the citizen suit.[200]

In making its decision, the Court considered two previous decisions on citizen suit provisions. In *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Foundation, Inc.*,[201] the Court held that the citizen suit provision under the CWA did not give plaintiffs standing to bring suits for wholly past violations based on the specific present-tense language of the provision, which authorized suits against persons alleged "to be in violation of the statute."[202] The Court found that this portion of the provision allowed citizen-plaintiffs to sue only so long as the defendant had not complied with its duties by the time the suit was filed, at least sixty days after the notice letter.[203] Further, because the Court found that Congress intended for citizen enforcement to merely be supplementary to the EPA's authority, it stated that allowing these claims would undermine the Agency's own discretion in pursuing claims against violators, and where necessary, making settlements.[204]

The second case, *Hallstrom v. Tillamook County*,[205] concerned the sixty-day notice portion of the citizen suit provision of RCRA, which the Court held to be a non-discretionary prerequisite to bringing citizen suits against facilities on the basis that it was meant to give the alleged violator an opportunity to remedy the violation, thus preempting the suit itself as per *Gwaltney*.[206] Thus, almost ten

199 *See* Coplan, *supra* note 187, at 326.

200 Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc., 484 U.S. 49, 57-58 (1987); *see also* Coplan, *supra* note 187, at 326 ("Courts have posited that the purpose of the notice and waiting period is to permit the defendant to come into compliance, to allow for government agency enforcement that would eliminate the need for a citizen suit, and to allow for settlement discussions between the would-be plaintiff and the violator.").

201 484 U.S. 49 (1987).

202 *Id.* at 57-58.

203 Most environmental citizen suit provisions require that citizen-plaintiffs file a notice letter to the relevant agency Administrator and to the violator, informing them of the specific claims. Plaintiffs must then wait sixty days after notice before commencing litigation. *See* Coplan, *supra* note 187, at 322.

204 *See* Gwaltney, 484 U.S. at 64.

205 493 U.S. 20 (1989).

206 *Id.* at 29.

years prior to *Steel Co.*,[207] the Court's general disposition on the scope of environmental citizen suits and the issue of past violations was well understood. The outcome of *Steel Co.* might have been predicted on the basis of these two cases, if not for the unique wording of the EPCRA citizen suit provision, and the Court's unexpected focus on the plaintiffs' constitutional standing.

The Sixth and Seventh Circuits divided over how to apply *Gwaltney* and *Hallstrom* to the EPCRA citizen suit provision, particularly because the provision is worded differently than the CWA provision. Post-*Gwaltney*, Congress amended the citizen suit provision of the Clean Air Act (CAA) to allow suits for past violations, leaving the sixty-day notice requirement intact for both government officials and violators.[208]

EPCRA's citizen suit provision, in relevant part, authorizes citizen suits against an owner or operator of a facility "*for failure . . . to complete* and submit an inventory form under section 11022 of this title . . . [and] section 11023(a) of this title."[209] This contrasts with the present-tense wording of the CWA discussed in *Gwaltney*, which allows suits against persons "alleged to be in violation" of the relevant provisions of the statute.[210] Like most of the environmental citizen suit provisions, however, EPCRA also mandates the sixty-day notice letter to the facility, the EPA, the state, and other relevant parties.[211]

The Sixth Circuit, in *Atlantic States Legal Foundation v. United Musical Instruments*,[212] found the difference in EPCRA's language insignificant and interpreted Congress' decision to allow suits for past violations under the CAA while maintaining the sixty-day notice requirement as a negative inference against allowing such suits where Congress has not explicitly allowed them.

In *Steel Co.*,[213] the Seventh Circuit came to the opposite conclusion. The citizen-plaintiffs, an environmental advocacy group, submitted a sixty-day notice letter to a steel manufacturer for failing, since the enactment of EPCRA in 1986, to submit the required TRI and toxic chemical release forms.[214] When the group filed suit at the end of the sixty-day period, the manufacturer filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), alleging that because it filed all of the missing forms after receiving the notice, the district

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207 Steel Co. v. Citizens for a Better Env't, 523 U.S. 83 (1998).

208 See Krista Green, An Analysis of the Supreme Court's Resolution of the Emergency Planning and Community Right-to-Know Act Citizen Suit Debate, 26 B.C. ENVTL. AFF. L. REV. 387, 408 (1999).

209 *See* EPCRA, 42 U.S.C. § 11046(a)(1)(A)(iii) (2006) (emphasis added).

210 33 U.S.C. § 1365(a) (1982).

211 *See* 42 U.S.C. § 11046(d).

212 61 F.3d 473, 477 (6th Cir. 1995).

213 Citizens for a Better Env't v. Steel Co., 90 F.3d 1237 (7th Cir. 1996), *vacated* 523 U.S. 83 (1998), *vacated* 151 F.3d 1032 (7th Cir. 1998).

214 *Id.* at 1241; 42 U.S.C. §§ 11022-11023.

court had no jurisdiction to hear the suit.[215] The district court held that it lacked jurisdiction under subsection 11046(c) over wholly past violations and dismissed the case.[216] The Seventh Circuit reversed, finding that the CAA's maintenance of the sixty-day notice requirement was evidence that the requirement was not simply gratuitous when citizen suits are allowed for historic violations of the statute.[217] Additionally, the Seventh Circuit found that as a policy matter, the informational mandates of the statute are minimal requirements for facilities such that "allowing citizen suits even for historical violations was permissible to ensure compliance." [218] Finally, the Seventh Circuit found that the citizen suit provision would be made "virtually meaningless" if citizens invested resources in pursuing violators and were then prohibited from suing.[219]

The Supreme Court granted certiorari, but declined to resolve the statutory dispute between the circuit courts. Reversing the Seventh Circuit's decision, the Court held that the plaintiffs lacked standing to pursue the suit based on the lack of redressability for its claims, the third prong for constitutional standing under Article III.[220] The opinion, which unanimously dismissed the citizen-plaintiffs' case for lack of jurisdiction,[221] has profound implications for the citizen suit enforcement provisions in monitoring regimes like EPCRA and the amended CAA. Whereas a defect in statutory standing can be remedied with a few words in a congressional revision, a defect in constitutional standing requires a structural revision that, while technically feasible, might reignite debates on the validity of citizen suit provisions altogether.

The alleged injury in *Steel Co.* was the deprivation of timely information on which the citizen-plaintiffs relied to "learn about toxic chemical releases [and] the use of hazardous substances in their communities, to plan emergency preparedness in the event of accidents, and to attempt to reduce the toxic

215 *Id.*

216 *Id.*

217 *See id.* at 1244-45.

218 *See* Green, *supra* note 208, at 422 (citing *Steel Co.*, 90 F.3d at 1240).

219 *Steel Co.*, 90 F.3d at 1245.

220 Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 109. (1998) Although plaintiffs suing under citizen suit provisions surpass the zone-of-interests test for prudential standing under a statute, they must still overcome the hurdle of constitutional standing under Article III. Plaintiffs must allege (1) an injury-in-fact, (2) causation, and (3) redressability. *See id.* at 103; Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-81, (2000).

221 There was a divergence between Justice Scalia and Justice Stevens about the order in which to decide the case. Justice Scalia maintained that the Court could not move forward with the statutory issue until it resolved whether the plaintiffs had Article III standing, and thus whether the Court had actual jurisdiction to hear the case. *See Steel Co.*, 523 U.S. at 89-102. Justice Stevens held firm that the statutory matter was also jurisdictional, and thus could have been resolved first. *See id.* at 113 (Stevens, J., concurring).

chemicals in areas in which they live, work and visit."[222] The citizen-plaintiffs made six claims for redress.

The first claim was for declaratory judgment that defendants violated EPCRA. The Court quickly disposed of this claim, stating that because there was no dispute that the defendant failed to file the reports and that the failure to file constituted a violation of the statute, "the declaratory judgment is not only worthless to respondent, it is seemingly worthless to all the world."[223]

The second claim was for authorization to inspect the defendants' facility and records. The Court dismissed this claim on grounds that it could only provide proper redress under Article III if the group had "alleged a continuing violation or the imminence of a future violation."[224]

The third was for an order to require the defendants to provide plaintiffs with copies of all of the compliance reports submitted to the EPA. The Court dismissed this claim on the same grounds as the second claim.[225]

The fourth claim was for a requirement for defendants to pay civil penalties of $25,000 per day for each violation of §§ 11022 and 11023. Perhaps most surprisingly, the Court dismissed this claim on grounds that it could not meet the Article III redressability requirement because the penalties are paid to the U.S. Treasury instead of the plaintiffs themselves.[226] The court explained:

> [A]lthough a suitor may derive great comfort and joy that the United States Treasury is not cheated, that a wrongdoer gets his just deserts, or that the Nation's laws are faithfully enforced, that psychic satisfaction is not an acceptable Article III remedy because it does not redress a recognizable Article III injury.[227]

The fifth claim was for award of costs for plaintiffs' investigation and prosecution of the case, including attorneys' fees and expert witness fees, authorized by section 326(f) of EPCRA. The Court dismissed this claim because the "plaintiff cannot achieve standing to litigate a substantive issue by bringing suit for the cost of bringing suit."[228] Investigative costs were dismissed as well,

222 *Id.* at 104-05 (majority opinion).
223 *Id.* at 106.
224 *Id.* at 108.
225 *Id.*
226 *Id.* at 106.
227 *Id.* at 107.
228 *Id.*

because section 326(f) only allows for compensation of the costs of litigation itself.[229]

The final claim was for further relief as the court deems appropriate. The Court did not address this claim.

The *Steel Co.* Court's rejection of civil penalties paid to the Treasury as redress for the plaintiffs not only contradicts common sense and precedent, as Justice Stevens asserts in his concurrence,[230] but also defies EPCRA's carefully crafted citizen enforcement scheme. Like its predecessors in the CAA and CWA, EPCRA's citizen suit provision was designed to expand the enforcement powers of the statute, while disallowing damages issued directly to citizen-plaintiffs;[231] civil penalties, particularly those amounting to $25,000 per day for each violation of the statute, are meant to compensate harm—mostly through the potential use of civil penalties for environmental initiatives—and to deter future harm, regardless of who receives the money. Thus, contrary to Justice Scalia's opinion, the citizen-plaintiffs in *Steel Co.* were not merely acting as faithful patriots seeking "the 'undifferentiated public interest' in faithful execution of EPCRA;"[232] they were also seeking to deter the industry from future failures to make timely filings of EPCRA data. Given the small likelihood of legal action by the overburdened EPA, the Court's decision to block citizen enforcement of the late filing penalties leaves little incentive for industries to file the information on their own. They can avoid submitting their information until they receive a sixty-day notice letter, and preclude a citizen suit by complying at that time.

Though Justice Stevens concurred in the judgment on the basis of the statutory language, he did not find error in plaintiffs' Article III redressability, citing private criminal prosecutions as historical precedent for similar redress[233] and assessing the consequences of denying redressability for the enforcement scheme of the statute:

> Under EPCRA, Congress gave enforcement power to state and local governments. 42 U.S.C. §11046(a)(2). Under the Court's reasoning, however, state and local governments would not have standing to sue for past violations, as a payment to the Treasury would no more "redress" the injury of these governments than it would redress respondent's injury. This would be true even if

229 *Id.* ("Respondent finds itself, in other words, impaled upon the horns of a dilemma: For the expenses to be reimbursable under the statute, they must be costs of litigation; but reimbursement of the costs of litigation cannot alone support standing.").

230 *Id.* at 126 (Stevens, J., concurring) ("Thus, as far as I am aware, the Court has never held—until today—that a plaintiff who is *directly injured* by a defendant lacks standing to sue because of a lack of redressability.").

231 *See* Coplan, *supra* note 187, at 321-22.

232 *Steel Co.*, 523 U.S. at 106.

233 *See id.* at 128-29 (Stevens, J., concurring).

> Congress *explicitly granted state and local governments this power.* Such a conclusion is unprecedented.[234]

In addition to dampening incentives for industries to follow the law, the *Steel Co.* decision penalizes citizen-enforcers. As stated by the Seventh Circuit in *Steel Co.*, citizen-plaintiffs typically incur great expenditures in time and resources to identify violators and to obtain enough information to make a good faith claim under the citizen suit provision.[235] Adding to these expenses the attorneys' fees and other costs of litigation places a substantial burden on plaintiffs not only to be reasonably certain that such violations occurred, but also to recover the costs and fees as relief after bringing an enforcement action.

Steel Co. strips away much of the citizen-plaintiff's incentive to pursue these suits. The risks of not recovering expenses and of imposing no penalties upon industries despite clear violations of the statute cut against pursuing claims at all. As the EPA and other environmental agencies reduce enforcement actions due to capacity or budget hardships, an absence of citizen suits leaves a void in the effective implementation of the statutory mandates.[236] In the *Steel Co.* opinion, Justice Scalia stated that the citizen-plaintiffs might have achieved necessary redress through their injunctive claims—inspections of facilities and copies of EPA compliance reports—if they had "alleged a continuing violation or the imminence of a future violation."[237] But such allegations must be predicated on sufficient evidence and good faith belief of their existence, which may not exist at the time of suit, even if it is likely that the facility will violate the statute sometime in the future.[238]

Ultimately, *Steel Co.* eroded the value of citizen enforcement for both the government and communities. Rather than reinforce Congress' decision to bolster the EPA's enforcement powers, the Court provided industries a way out of effective compliance with the statute, quite literally at the expense of the people it was meant to serve.

Finally, the *Steel Co.* decision frustrates the purpose and scheme of the statute. Embodied in the four central mandates of the EPCRA are two

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234 *Id.* at 129-30.

235 *See* Citizens for a Better Env't v. Steel Co., 90 F.3d. 1237, 1245 (7th Cir. 1996), *vacated* 523 U.S. 83 (1998), *vacated* 151 F.3d 1032 (7th Cir. 1998).

236 *See generally* James R. May, *Now More than Ever: Trends in Environmental Citizen Suits at 30*, 10 WIDENER L. REV. 1 (2003) (discussing the negative impacts of slashed enforcement budgets and changed priorities, particularly related to national security, on the rates of environmental enforcement actions brought by agencies like EPA and the Department of Justice).

237 *Steel Co*, 523 U.S. at 108.

238 *See* Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc., 484 U.S. 49, 66-67 (1987). The Court held that the language of the CWA citizen suit was intended to enjoin continuous or intermittent violations rather than wholly past violations. To maintain standing, therefore, citizen-plaintiffs must make "a good-faith allegation of an ongoing violation." *Id.* at 67.

overarching purposes: publishing accurate, reliable information on the presence and release of toxic chemicals at a reasonably localized level; and using the reported information to formulate local emergency response plans.[239] The statute clearly lays out annual deadlines for the submission of the information.[240] As discussed above, the data are meant to be utilized far beyond the EPA, and have transformed the ability of scientists, policymakers, community environmentalists, businesses, and others to monitor environmental and public health hazards, propose informed policies for reducing toxic storage and emissions, and create emergency plans that effectively mitigate the devastation of hazardous accidents.[241] Because the value of information is so tightly connected to its timeliness for the purposes of the statute, communities' hazard reduction and disaster prevention efforts will be impaired if they have difficulty obtaining correct and current information, irrespective of any transformative measures to streamline and democratize data access.

Though *Steel Co.* does not reach the question of whether the untimeliness of information constitutes an injury-in-fact for citizen-plaintiffs under EPCRA,[242] the decision that such a claim could not be redressed had the same effect as denying the existence of the injury itself.

Further, even if the Court chose to decide the question of jurisdiction under the statute first, thereby avoiding the question of constitutional standing, it is clear from the concurrence written by Justice Stevens and the Court's precedent on the subject that it would likely have dismissed the case for lack of statutory jurisdiction as well.[243] Justice Stevens, aiming at the circuit split, scrutinizes the language of the citizen suit provision, the sixty-day notice requirement, and the supplemental role of citizens in the EPCRA enforcement scheme, ultimately siding with the Sixth Circuit's interpretation.[244] Although he acknowledges that the language of the provision—"failure . . . to complete and submit"[245]—is ambiguous, he resolves the interpretive issue with the notice requirement and supplemental authority role,[246] ignoring the implications of the CAA amendments to the former and the "diligent prosecution" safeguard to the latter.

It is unclear, for example, why Congress could not have intended the sixty-day notice to give owners/operators an opportunity to correct violations of the statute so as to avoid *prospective* accruals of penalties, which are assessed on a

239 *See* EPCRA, 42 U.S.C. §§ 11001-11023 (2006).

240 *See, e.g., id.* § 11023(a) (requiring facilities to submit their release reports by July 1 of every year).

241 *See* HAMILTON, *supra* note 10, at 208.

242 *See Steel Co.*, 523 U.S. at 105.

243 *See id.* at 132-34 (Stevens, J., concurring).

244 *See id.*

245 *Id.* (alteration in original) (quoting Atl. States Legal Found. v. United Musical, 61 F.3d 473, 475 (1995)).

246 *Id.*

daily basis.[247] This would provide benefits to both parties by compelling the information and preventing increased liability, while maintaining the necessary deterrence mechanism by allowing plaintiffs to recover penalties accrued during the period of non-compliance. Further, it has been suggested that the sixty-day provision is intended to give government time to decide whether to prosecute on its own, thus precluding the citizen suit, and also to allow the citizen-plaintiffs and the violators time to reach a settlement.[248] Indeed, although Justice Stevens was concerned with the intrusion of citizen-plaintiffs on the EPA's regulatory discretion, it is unclear why the scenario he suggests—EPA negotiating a settlement with a party and citizen-plaintiffs interfering with subsequent lawsuits against the same party for the same issues—would not be precluded by the "diligent prosecution" provision of the statute, which disallows citizen suits when the EPA or possibly the state is taking its own enforcement measures against violating parties.[249] Though there may be some legal disputes between citizens and governing entities as to what constitutes "diligent prosecution," particularly when settlements are made to incorporate multiple claims that plaintiffs could litigate, those conflicts could be resolved in court or by negotiation on a case-by-case basis without depriving citizen-plaintiffs of the ability to sue for historic violations.

The informational mandates of EPCRA are the drivers of the statute, and emergency prevention and hazard reduction are the purpose; if the information is not reliable and timely, then the statute is defunct. If the timeliness of the statutorily required information can only be enforced by the agency, then many communities are left without a viable alternative for managing non-compliant industries, other than suing the agency for non-enforcement or spending money and time monitoring companies and threatening them with lawsuits to force them to file within the sixty-day notice period. A statute so heavily purposed for the non-governmental community should not unnecessarily narrow the available avenues for the community to obtain the information to which it is entitled.

It is important to note that that there are no records of EPCRA citizen suits filed by plaintiffs in Institute.[250] Nixon and Nye both asserted that the litigation related to industry malfeasance, such as the cases brought by Davis, Willis, and

247 After outlining the civil penalties for violating EPCRA's reporting requirements, the statute specifies that "[e]ach day a violation . . . continues shall, for purposes of this subsection, constitute a separate violation." EPCRA, 42 U.S.C. § 11045(c)(3) (2006). Counting each day as a separate violation could reasonably be interpreted to decouple past infringement from the potential for future harm.

248 *See* Coplan, *supra note* 187, at 326.

249 *See id.* at 329-31. Also, in this case, EPA decided not to pursue an enforcement action against Steel Co., despite the fact that the company had failed since EPCRA's inception to adhere to the requirements. *See Steel Co.*, 523 U.S. at 87.

250 Email from Pam Nixon, *supra* note 142; Email from Maya Nye, *supra* note 81. There were no electronic records of such suits from Institute.

Ferguson, have been common law toxic torts claims, despite the fact that Bayer has frequently violated the statute.[251] Though there are a number of reasons why Institute residents may have chosen not to bring suits under EPCRA—lack of resources, no damages, strategic alternatives—the citizen suit provision is nonetheless an important power to preserve, even if only as a means to obtain information pertinent to developing other lawsuits.

Considering these challenges, the *Steel Co.* decision ultimately requires an amendment to EPCRA's citizen suit provision that will cure the redressability problem for past violations. The challenge, as mentioned above, is the fact that such a change will require plaintiffs to pursue more than a nominal or hypothetical remedy. The revisions to the CAA citizen suit provision, for instance, are also dubious as to redressability, even though Congress intended to confer statutory standing for wholly past violations. Allowing citizen suits under the CAA for persistent historic violations[252] does not cure the Article III standing problem, as the typical remedy—penalties to the U.S. Treasury—are no different than those under EPCRA and most other environmental citizen suit provisions. However, Congress' additional citizen remedy under the CAA, a Supplemental Environmental Project (SEP) for up to $100,000 in lieu of penalties to the U.S. Treasury,[253] would very likely cure the redressability problem, so long as it was aimed at the plaintiffs' community. Alternatively, Congress could always decide to allow citizen-plaintiffs to collect at least a portion of the civil penalties outlined under the statute. Such an amendment could be positive for communities in need of funding for LEPCs, training workshops, and other emergency planning initiatives. Although it cuts against the original reasoning for allocating the penalties to the Treasury, it might be the only way to resolve the issue, presuming that SEPs cannot all be specifically located in the violated community. Regardless of the specific revision chosen, Congress must act to preserve citizen suit enforcement authority under EPCRA and other environmental statutes.

CONCLUSION

EPCRA exists to balance power between communities and the industrial facilities in and around them. That Institute and Bhopal were at the forefront of the legislation is no coincidence; both communities suffered tremendously not only because they were physically surrounded by volatile industries, but also because they lacked the knowledge and political power to protect themselves from the risks inherent in the places where they lived.

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251 Email from Pam Nixon, *supra* note 142; Email from Maya Nye, *supra* note 81; *see also* Interview with Warne Ferguson, *supra* note 43.

252 42 U.S.C. § 7604(a) (2006) (Citizen suits may be brought against anyone "who is alleged to have violated (if there is evidence that the alleged violation has been repeated) or to be in violation" of emission standards.).

253 *See* Coplan, *supra* note 187, at 323.

Congress' decision to eschew its traditional "command and control" measures in favor of a public information mandate shifted the center of regulatory power from the agency to the community, giving the public access to information they could use to strengthen public and environmental health. Indeed, as seen in the Institute context, having such data is imperative to keeping critical issues in the public eye after the sensationalism of a major disaster dissipates. Further, mandating nationwide emergency preparedness that includes participation of community members and industry representatives creates opportunities for meaningful, collaborative relationships between parties that quite often operate in opposition to one another.

In this sense, EPCRA is fundamentally rooted in the principles of environmental justice: its purpose is to promote the public interest in obtaining critical information for important decisions about where to live, play, and work, and how to protect the health of a community. Its challenges are also rooted in equity considerations—ensuring that citizens are able to hold industries accountable for their actions, and highlighting the disparities in emissions and public health outcomes in different communities, focusing particularly on impacts in low-income communities and communities of color. New technology and expanding knowledge enable innovative tools to improve understanding of the impacts of industry on the health and welfare of communities and the environment. It is imperative that the EPA and other developers of these resources critically evaluate measures to improve their accessibility and usability for the general public, such that the community right to know is not contingent upon access to specific expertise, technology, or resources.

Similarly, the right to emergency preparedness should not hinge upon whether communities can obtain financial or in-kind contributions from local businesses and industries or compete for federal funding. Leaving this vital, Congressionally mandated community function without the necessary basic operational resources seems at cross-purposes with Congress' persistent occupation with homeland security and creates inequitable outcomes for communities with fewer resources. Congress must adequately fund the statute if the challenges identified by Nixon and the LEPC surveys are to be resolved in order to properly protect communities and national security.

Finally, as enforcement is imperative for the execution of all provisions of this statute, the *Steel Co.* decision warrants revisions to the citizen suit language to ensure that citizens may enforce against wholly past violations. This involves curing the Article III standing defects, as well as addressing the statutory jurisdiction issue raised by Justice Stevens in his concurrence. This will protect communities by deterring abuse of the statute.

The growing body of scholarship on the linkages between environmental hazards and public health highlights the need for policymakers to begin allocating more resources to environmental health research and to revisit statutes like EPCRA, which contribute to understanding how—and to what extent—

industries impact human health. As mentioned at the beginning of this Note, EPCRA's potential is immense: there are few laws that can contribute so much relevant information to both academia and industry, while simultaneously empowering citizens with tools to both resist the abuses and overindulgences of powerful companies and plan for a range of emergencies. There is indeed a way for all stakeholders to gain under the statute—a rare outcome in the political arena. As such, there is no justifiable reason not to make the revisions required to bring the statute to its full potential, and there is similarly no strong reason for its implementation to not prioritize citizen awareness—it is after all, premised on the public right to know. Congress has an obligation to act, and it must continuously and consistently invest in EPCRA.