

SCIENTIFIC SUBSTANTIATION OF MECHANISMS FOR IMPLEMENTING A HEALTH INSURANCE SYSTEM

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ABSTRACT. The relationships between health insurance and access to health care, and health insurance and care received, have been the subject of hundreds of studies over the past several decades. More recently, the relationship between health insurance and health outcomes has also been examined. This chapter describes the Committee's analytic approach to its critical review of this research to inform the understanding of the relationships between health insurance, health care, and health outcomes for adults.

The chapter is organized in three sections. First, it outlines the mechanisms by which the Committee postulates that health insurance affects health-related outcomes. Whether one has health insurance, a regular source of care and, if one is uninsured, the length of time that one is without coverage all influence access to care and affect health-related outcomes.

The second section discusses issues related to the measurement of health insurance effects and considerations of research design that affect the inferences that can be drawn. It explores analytic strategies to distinguish the effects of health insurance status from those of personal attributes that are correlated with health insurance, including health status, race and ethnicity, and socioeconomic status, which may confound the results of studies that relate health insurance to health outcomes. The section gives particular attention to the two-way causal relationship between health status and insurance status.² It also describes the major population surveys and databases that provide information about Americans' use of health care and epidemiological information about health status and disease prevalence. These sources provide the data for many of the most informative studies reviewed.

Health insurance facilitates access to health care by removing or diminishing financial barriers to obtaining care. Among people who have insurance, the extent of cost sharing also influences the use of health care (Newhouse et al., 1993; Zweifel and Manning, 2000). An extensive body of research consistently finds a strong and positive relationship between health insurance and access to care, even as the definitions and measures of access have been strengthened. Population-based surveys conducted over the past three decades have evaluated access to primary care in relation to health insurance status with measures such as any physician visit within a year, the number

of physician visits per year, having a regular source of care, and the ability to obtain care when needed (Freeman and Corey, 1993; Hafner-Eaton, 1993; Newacheck et al., 1998; Nelson et al., 1999; Zuvekas and Weinick, 1999; Haley and Zuckerman, 2000; Kasper et al., 2000; Shi, 2000; Weinick et al., 2000; Hoffman et al., 2001).

Public policy and health care industry interests in high-quality and efficient health care have developed in tandem with the progress of clinical effectiveness research over the past decade. The standards of evidence for the efficacy of health insurance in promoting better health outcomes have evolved from enumerating physician visits to measurable improvements in effective processes of care. The notion of “access” itself has shifted from a simple measure of utilization to measures that incorporate the quality of care and health outcomes. In 1993, the Institute of Medicine (IOM) Committee on Monitoring Access to Personal Health Care Services reconceptualized access as “the timely use of personal health services to achieve the best possible health outcomes” and recommended a set of health outcome measures that could serve to monitor populations over time for access to basic health services (Millman, 1993).

In studies of access to care and health outcomes, several factors mediate the relationship between health insurance and health-related outcomes. These include being able to see a provider when one believes care is needed, having a regular source of health care, having continuity of coverage, and the duration of periods without health insurance. Measures for each of these factors provide some information about an individual's or population's access to health services that supplements the measurement of health insurance status at a given point in time. These measures are discussed below.

The ability to see a physician or other health care provider when one believes medical attention is needed is a fundamental and intuitive measure of access to health care. Most Americans mistakenly believe that people without health insurance have this level of access (IOM, 2001a). Although the lack of health insurance is not the only reason someone might not be able to see a health care practitioner when needed, it is a major one.³ Adults without health insurance are far more likely to go without health care that they believe they need than are adults with health insurance of any kind (Lurie et al., 1984, 1986; Berk and Schur, 1998; Burstin et al., 1998; Baker et al., 2000; Kasper et al., 2000; Schoen and DesRoches, 2000; Davidoff et al., 2001; Holahan and Spillman, 2002).

While the overall percentage of adults who reported that cost prevented them from seeing a doctor in the previous 12 months increased only slightly from 10 percent to 11 percent between 1991 and 1996, the proportion of uninsured adults who reported this barrier to care increased from 28 to 35 percent, and the fraction of insured adults reporting this barrier decreased slightly from 8 to 7 percent (Nelson et al., 1999).⁴ In 1998, nearly 70 percent of uninsured adults in poor health could not see a doctor at

some time during the year because of cost (Ayanian et al., 2000). A study that polled 1,100 patients four months after their initial visit to an emergency department found that patients who lost their health insurance were more than twice as likely as those who maintained their coverage to have delayed seeking care in the four-month interval (Burstin et al., 1998).

Evaluations based on professional judgment confirm findings based on a subjectively determined need for care. In one study with a national probability sample of almost 3,500 adult respondents, a physician panel identified 15 serious conditions for which they deemed medical attention necessary (Baker et al., 2000). In an analysis that adjusted for demographic and economic characteristics and also for health status and having a regular source of care, the authors found that an uninsured adult was much less likely than an insured adult to get care for a reported symptom (odds ratio [OR] = 0.43). Examining only those symptoms for which the respondent thought care was needed, those without insurance were even less likely to have received care (OR = 0.28). Among those who did not receive needed care, the uninsured were far more likely than those with insurance to report that they did not get care because of cost (95 percent and 23 percent, respectively) (Baker et al., 2000).⁵

A lack of health insurance acts not only as an initial barrier to care but may continue to impede the receipt of appropriate, effective care. Even if uninsured patients receive primary care, referrals to specialists, ancillary diagnostic and treatment services and medications are more difficult to obtain. Primary care providers who treat uninsured and other low-income patients report greater difficulty in arranging for referrals and services that they cannot directly provide for their uninsured patients than for those who are insured (Fairbrother et al., 2002).

Persons who never present themselves to a health care provider are not accounted for in health services research that documents and measures utilization and outcomes with hospital administrative records, patient chart reviews, and clinic encounter forms. This is a “blind spot” and source of bias in studies of health insurance effects because overall, persons without health insurance are estimated to use roughly two-thirds of the services that those who do have insurance use (Marquis and Long, 1995). Because those without health insurance are less likely to see a provider than are others with insurance and thus are less likely to be included in research documentation, studies that rely on health care records to compare groups who received some care may overstate utilization by uninsured populations.

Having a Regular Source of Care

In addition to supplying the financial resources that enable one to obtain health care when needed, insurance coverage also improves receipt of appropriate care by facilitating the use of a regular source of care or primary care provider.⁶ Both health insurance and having a regular source of care contribute independently to the utilization

of health services (Solis et al., 1990; Mosen et al., 1998; Mandelblatt et al., 1999; Zuvekas and Weinick, 1999; Cummings et al., 2000; Breen et al. 2001). Having a regular source of care enhances the appropriate use of ambulatory care as measured by receipt of preventive services, management of chronic conditions, and population rates of avoidable hospitalizations (Bindman et al., 1995; Starfield, 1995; Pappas et al., 1997; Kozak et al., 2001).

The independent contribution that having a regular source of care makes to the receipt of appropriate care reinforces rather than diminishes the importance of health insurance, because health insurance is an important determinant of obtaining and maintaining an ongoing relationship with a health care provider. Adults with health insurance are much more likely than those who are uninsured to have a regular source of care, a consistent finding across states with very different health care resources and provider configurations (IOM, 2001a; Holahan and Spillman, 2002). An analysis based on the 1997 National Health Interview Survey found that among adults eligible for Medicaid, 42 percent of those not enrolled in the program did not have a regular source of care, whereas only 12 percent of those with Medicaid coverage lacked one (Davidoff et al., 2001). Even those uninsured adults who have chronic conditions are substantially more likely to lack a regular source of care than are chronically ill adults with health insurance. Among uninsured adults, 19 percent with heart disease, 14 percent with hypertension, and 26 percent with arthritis do not have a regular source of care, compared with 8, 4, and 7 percent, respectively, of their insured counterparts (Fish-Parcham, 2001).

Someone without health insurance who can identify a regular source of care may still face difficulties in obtaining recommended and effective health care services that are outside the scope of practice of their regular provider, such as referrals to specialists, ancillary services, and hospital-based care.

REFERENCES

- [1] Section 5 of the FTC Act prohibits “unfair or deceptive acts or practices in or affecting commerce,” and Section 12 prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics. 15 U.S.C. §§ 45, 52. Section 15 of the FTC Act defines “false advertisement” as “advertising that is misleading in a material respect[.]” 15 U.S.C. § 55(a)(1).
- [2] See FTC Policy Statement on Deception, appended to Cliffdale Assocs., Inc., 103 F.T.C. 110, 174 (1983), <https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception> (“Deception Policy Statement”); FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Med. Co., 104 F.T.C. 648, 839 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986), <https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation> (“Substantiation Policy Statement”).

- [3] See discussion at Section III.B.
- [4] See, e.g., Complaint at 7, *FTC v. Sunrise Nutraceuticals, Inc.*, No. 9:15-cv-81567 (S.D. Fla. Nov. 16, 2015) (stipulated final judgment) (claims made in a press release and on website); Complaint at 5-24, *FTC v. NourishLife, LLC*, No. 1:15-cv-00093 (N.D. Ill. Jan. 7, 2015) (stipulated order) (claims made in social media, sponsored links, brochures, product packaging, emails, and websites); Complaint at 5-13, *FTC v. Sensa Prods., LLC*, No. 1:14-cv-00072 (N.D. Ill. Jan. 7, 2014) (stipulated final judgment) (claims made in a book, infomercials, print and radio ads, and email); Daniel Chapter One, 148 F.T.C. 832, 904-35 (2009) (initial decision) (“Daniel Chapter One Initial Decision”) (claims made in radio programs, newsletter, catalog, and website).
- [5] For a discussion of the five factors that determine whether speech is commercial, see *POM Wonderful, LLC*, 155 F.T.C. 1, 74-75 (2013) (citing *R.J. Reynolds Tobacco Co.*, 111 F.T.C. 539, 544-46 (1988)), *aff’d in part*, *POM Wonderful LLC v. FTC*, 777 F.3d 478, 504-05 (D.C. Cir. 2015).
- [6] See, e.g., *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 167-73 (2d Cir. 2016) (affiliate advertising network); *POM Wonderful, LLC*, 155 F.T.C. at 82-84 (individual officer); *FTC v. Fitness Brands, Inc.*, No. 1:12-cv-23065-CMA (S.D. Fla. Aug. 23, 2012) (stipulated final judgment) (infomercial host); *Dreher*, 150 F.T.C. 560 (2010) (consent order) (expert endorser); *Campbell Mithun LLC*, 133 F.T.C. 702 (2002) (consent order) (ad agency); *Tru-Vantage Int’l, LLC*, 133 F.T.C. 299 (2002) (consent order) (infomercial producer).
- [7] See *Novartis Corp. v. FTC*, 223 F.3d 783, 787-88 (D.C. Cir. 2000) (corrective advertising is appropriate where challenged ads played a substantial role in creating or reinforcing a false belief about a product and that misbelief is likely to linger).
- [8] See, e.g., Memorandum Opinion and Order at 10, *FTC v. Kevin Trudeau*, No. 1:03-cv-03904 (N.D. Ill. Aug. 7, 2008) (imposing three-year ban on Trudeau from participating in any infomercial for any product).
- [9] Memorandum of Understanding Between the Fed. Trade Comm’n and the Food and Drug Admin., 36 Fed. Reg. 18,539 (Sept. 16, 1971), www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm.
- [10] Some forms of marketing may constitute both labeling and advertising under the two agencies’ laws. For example, a website where a dietary supplement can be purchased would fall within the FDA’s definition of labeling in addition to being advertising under FTC law.
- [11] DSHEA amended the Federal Food, Drug, and Cosmetic Act (FDCA). Pursuant to DSHEA, “structure/function” refers to an FDA regulatory term for a category

of labeling claims that describe the normal structure or function of the human body or general well-being. Under FDA law, such claims must be truthful, not misleading and substantiated, but do not require prior FDA review or approval. See Structure/Function Claims, Fed. Drug Admin. (last updated Dec. 14, 2017), www.fda.gov/food/food-labeling-nutrition/structurefunction-claims. The term has no legal significance under FTC law relating to claim substantiation.

- [12] See Daniel Chapter One, 148 F.T.C. 832, 1086 (2009) (finding no authority that the DSHEA amendment to the FDCA regarding “structure/function” claims is binding on the Commission), *aff’d*, 405 Fed. App’x 505 (D.C. Cir. 2010).
- [13] *Id.* at 1085-86 (rejecting Respondents’ argument that the FDCA distinctions between foods, drugs, or dietary supplements are binding on the FTC’s enforcement of Sections 5 and 12 of the FTC Act). See also *FTC v. NPB Advert., Inc.*, 218 F. Supp. 3d 1352, 1365 n.4 (M.D. Fla. 2016) (passage of DSHEA “imposes no duty on the FTC in this false advertising action”); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) (“FDA requirements and regulations . . . simply do not govern this case”).
- [14] See Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, 28,393-94 (June 1, 1994), www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising (“Food Advertising Policy Statement”).
- [15] *Id.*
- [16] In 2008, the FDA issued a guidance document detailing how it evaluates substantiation for structure/function claims in dietary supplement labeling, stating, “The FTC has typically applied a substantiation standard of ‘competent and reliable scientific evidence’ to claims about the benefits and safety of dietary supplements and other health-related products. FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach.” Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, Food and Drug Admin. (Jan. 2009), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food>.
- [17] *Novartis Corp.*, 223 F.3d at 787; *Kraft, Inc.*, 114 F.T.C. 40, 121-22 (1991), *aff’d*, 970 F.2d 311 (7th Cir. 1992).
- [18] Deception Policy Statement, 103 F.T.C. at 174-75, 179. See also *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1385 (M.D. Fla. 2018); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008), *aff’d*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat’l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008); *Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989).