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THE FDA AND PLAN B:

The Legislative History of the Durham-Humphrey Amendments and the Consideration of Social Harms in the Rx-OTC Switch

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ABSTRACT

The 1951 Durham-Humphrey Amendments limited the FDA's power over the Rx-OTC decision by enacting an objective definition of a prescription drug that would be applied primarily by drug manufacturers. Under this regime, Congress likely intended the Rx-OTC decision to be limited to consideration of medical or scientific harms so as to insure the most limited role for the FDA, maximize the ability of the public to self-medicate, and insure consistency in different manufacturer's Rx-OTC determinations. However, the 1962 Drug Amendments expanded the FDA's power regarding Rx to OTC switches by requiring the FDA to balance the costs and benefits of a drug to determine whether it was in the best interest of society for the drug to be marketed OTC. Thus, social harms are appropriate considerations for the Rx-OTC decision if they are true societal costs of a drug, specifically, if they are quantifiable, generally accepted, and a reasonable

probability. Applying these lessons to the proposed Rx to OTC switch of the emergency contraceptive Plan B, the FDA seems to have exceeded its authority by considering social harms—increased teen promiscuity and decreased teen condom use—that are not reasonably probable. Moreover, by failing to acknowledge that it was considering social harms the FDA threatened the transparency necessary to administrative accountability.

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I.

"I can assure you that this decision will not be based on politics. It will be based on science," said then-Acting Commissioner of the Food and Drug Administration ("FDA") Leslie Crawford in the Senate hearings on his nomination to be Commissioner.[1] He was referring to the FDA's determination as to whether to approve Plan B, an emergency contraceptive commonly referred to as the "morning-after pill," for over-the-counter ("OTC") sale.[2] The Plan B decision is perhaps the most controversial decision the FDA has ever made. It has sparked intense scrutiny of the FDA by the media, members of Congress, social conservatives, and reproductive rights advocates. It has won the FDA praise from pro-life advocates and those favoring "traditional" social values, while at the same time it has led to criticism of the FDA from liberals and

[1]Gardiner Harris, *F.D.A.'s Role in Delaying Contraceptive is Criticized*, N.Y. Times, March 18, 2005, at A16, 2005 WLNR 4194704.

[2]Plan B was approved for prescription use in 1999 and consists of two pills of levonorgestrel, a synthetic hormone found in birth control pills. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *FDA's Decision Regarding Plan B: Questions and Answers* (2004), at 1, at http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm [hereinafter *Plan B Q&A*]. Plan B primarily acts to prevent ovulation, but it may also prevent fertilization or implantation of a fertilized egg in the womb. *Id.* The first pill should be taken as soon as possible after intercourse, but no more than 72 hours later, and the second pill should be taken 12 hours after the first. *See* Marcia Crosse, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual*, GAO Rep. No. 06-109, at 12 (2006), http://www.gao.gov/new.items/d06109.pdf [hereinafter *GAO Report*]. Plan B can reduce the risk of pregnancy by 89% when used within 72 hours of intercourse. *Id.*

those committed to reproductive "freedom." It has caused internal divisions within the FDA, including the resignation of the senior FDA official responsible for women's issues. It has delayed the confirmation of two different nominees for FDA Commissioner. And it has led to an administrative impasse within the FDA. As of May 2006, it had been 16 months since the target date for the FDA's second decision on Plan B and over three years since the OTC switch was first proposed and yet no final decision had been made.

Despite Dr. Crawford's assurances, many observers, both within the FDA and in the general public, believe that the delay on Plan B and the actions that the FDA has taken thus far were motivated by political considerations and concerns over social issues unrelated to medical or scientific harm. In particular, they allege the decision (or lack thereof) is influenced by the opposition of the Bush Administration and social conservatives to abortion or, at the very least, dislike by these same groups of increased sexual activity.[3] This raises interesting and important questions that this paper endeavors to answer: what are the appropriate factors for the FDA to consider in making the prescription ("Rx") to OTC decision? Specifically, is the FDA limited to considering medical or scientific evidence and harms or can it also consider questions of social policy and social harms?

Answering these questions involves the difficult task of separating social harms from medical and scientific harms. Unfortunately, there is no clear line where questions of science or medicine give way to questions of morality and social policy. Perhaps the best definition that can be formulated, and one that works effectively in the vast majority of cases, is the definition used by Justice Potter Stewart to define hard core pornography: "I know it when I see it. . . ."[4] Certain questions are clearly medical or scientific (does the drug's toxicity make it dangerous? will the drug interact dangerously with other drugs?) while other questions are clearly social

[3] *See* Editorial, *Science or Politics at the F.D.A.?*, N.Y. Times, Feb. 24, 2004, at A24, 2004 WLNR 5575199.
[4] Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

(will Rx or OTC make the drug the most affordable to consumers? will a switch to OTC status make the drug unprofitable and thereby discourage development by the pharmaceutical industry?). As to cases where Justice Stewart's definition provides no help, a rough line can be drawn: medical/scientific harms relate to effects on the body while social harms relate to effects on the behavior of the relevant actors (consumers, doctors, pharmaceutical companies, politicians, etc.).

Unsurprisingly, given the controversy it has engendered and the difficulty the FDA is having in making a decision, the major concerns over Plan B do not easily fall into either category. At least one concern supporters of OTC status for Plan B allege is motivating the FDA's decision[5] is easily categorizable as a social harm: the opposition of social conservatives and the Bush White House based on their dislike of abortion. However, the main concerns asserted by the FDA, that easier access to Plan B will increase teen promiscuity and decrease teen condom use,[6] toe the line between science or medicine and social harms. On their face, they appear to be questions of social harm because they relate to the behavior of Plan B's consumers. There is nothing inherently threatening to the body about teen sexual activity; its appropriateness depends on a person's view of morality and social issues. Likewise, decreased condom use does not cause direct harm to the body. However, just below the surface, these questions are closely tied to science and medicine. A major concern about teen promiscuity and decreased condom use is that they will lead to an increase in STD transmission, which, like increased incidents of any disease, is clearly a medical question because of the negative effect on the body. Thus, the concerns raised by the Plan B debate range the spectrum from clearly social (opposition to abortion) to likely social (increased promiscuity and decreased condom use) to clearly medical (increased transmission of STDs). Despite its inexactness, a relatively effective line between medical/scientific harms and social harms can be drawn for purposes of this paper.

[5] *See* Rita Rubin, *Plan B Decision Called Political,* USA TODAY, May 9, 2004, http://www.usatoday.com/news/health/2004-05-09-fda-morning-after_x.htm.

[6] *See GAO Report, supra* note 2, at 5.

In the original 1938 Food, Drug, and Cosmetic ("FD&C") Act, the decision as to whether a drug was prescription-only or available for OTC sale—and thus, the decision as to what factors to consider—was left primarily to the manufacturer, a regime that was essentially left in place by the 1951 Durham-Humphrey Amendments, the legislation that provided the current definition of a prescription drug.[7] However, the 1962 Drug Amendments, among many other changes, required the FDA to approve all new OTC drugs and review all OTC drugs introduced to the market since 1938.[8] This gives the FDA the role of determining what criteria to consider in making the Rx-OTC decision and applying the Durham-Humphrey Amendments' standard, which currently defines a prescription drug as: 1) a drug which is not safe for use except under professional supervision "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use"; 2) a drug which is limited by its new drug application ("NDA") to use under professional supervision.[9] The first provision contains the real definition of a prescription drug and will be the focus of this paper since the second provision merely covers new drugs that meet this definition.[10] Now days, almost all new drugs are originally limited to prescription-only sale for several years, and a manufacturer seeking to switch a drug to OTC status after this period will submit a supplemental NDA, requiring the FDA to apply the definition of a prescription drug to make its decision.[11]

The starting point for the inquiry as to whether the FDA can consider social harms in making the Rx-OTC decision, like many questions of statutory interpretation that lack clear textual answers, is the legislative history of the definition of a prescription drug, and Part II provides a detailed legislative history of the

[7] *See infra,* Part IIA, Section 1; *infra*, Part IIB, Section 3.

[8] *See* Peter Temin, Taking Your Medicine: Drug Regulation in the United States 125 (1980); W. Steven Pray, A History of Nonprescription Drug Regulation 171 (2003).

[9] 21 U.S.C. §353(b)(1) (2006). The definition of a prescription drug in the Durham-Humphrey Amendments also included those drugs designated as habit-forming under a different provision of the FD&C Act. Durham-Humphrey Amendments of 1951, Pub. L. No. 82-215, §1, 65 Stat. 648, 648 (1951) (amended 1997). This provision was eliminated in 1997, *see* Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, Title I, § 126(c), 111 Stat. 2328 (1997). Neither it nor the reasons for its elimination are relevant to this discussion.

[10] *See* Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status,* 37 Food Drug Cosm. L.J. 427, 433 (1982).

[11] *See* David E. Collins, *Report of the Task Force on the Future of OTC Drugs*, 55 Food & Drug L.J. 27, 27 (2000).

Durham-Humphrey Amendments. It describes the efforts of the pharmaceutical industry and its Congressional supporters to achieve uniformity in the Rx-OTC determination by taking the initial decision away from the manufacturers and giving it to the FDA. This effort failed in the face of a successful counter-effort by the pharmaceutical industry and its Congressional supporters to avoid an administrative determination. Part III takes a broader view of the legislative history, identifying four main goals of Congress—to restrain the power of the FDA, to enact an objective rather than administrative definition, to promote self-medication, and to eliminate reference to efficacy—that all suggest that the Rx-OTC determination was meant to be limited to consideration of medical and scientific harms, rather than social harms. Although the textual language is broad and unclear, leaving room for reasonable assertions that social harms are an appropriate consideration, Part III suggests that nothing in the specific language of the definition is strong enough to overcome the contrary conclusion from the four Congressional goals.

Part IV applies the lessons learned from the legislative history of the Durham-Humphrey Amendments to conclude that the FDA's rejection of OTC status for Plan B violated the legislative intent of the Durham-Humphrey Amendments. However, Part V advocates a limited departure from this legislative history because the 1962 Drug Amendments delegated to the FDA greater authority over the Rx-OTC decision than was given in 1951. Since this departure is only justified to the extent necessary to exercise the greater powers given to the FDA in 1962, only social harms that reflect real costs to society that the FDA must balance to determine whether OTC marketing of a drug is in the best interest of society—namely, those that are quantifiable, generally recognized as harmful, and reasonably probable—should be considered in the Rx-OTC decision. Part V concludes that the FDA inappropriately considered social harms that were not reasonably probable in rejecting Plan B's OTC application, and, moreover, undermined the transparency necessary for administrative accountability by failing to forthrightly admit that it was considering social harms.

II.

A.

Background to the Durham-Humphrey Amendments

1.

The Development of a Prescription-Only Class of Drugs

Although prescriptions pre-dated the 20^{th} century, the concept of a mandatory class of prescription drugs is purely a creature of the past one hundred years. Nineteenth-century drug laws, as well as the Biologics Act of 1902[12] and the Food and Drugs Act of 1906,[13] focused on the quality of drugs without addressing their availability.[14] In 1914, the Harrison Narcotics Act created a mandatory class of prescription-only drugs, though that class was limited to specific narcotic drugs.[15] Thus, as Congress took up consideration of a new food and drug law in the 1930s, prescriptions were a possibility but not a requirement—a person could buy any non-narcotic drug from a pharmacy for self-medication without ever having seen a doctor.[16]

The FD&C Act of 1938[17] for the first time drew a general distinction between prescription and nonprescription drugs. Section 503(b) exempted "drugs dispensed on a written prescription" from certain limited labeling requirements.[18] While this provision provided an incentive towards the creation of a prescription-

[12] 32 Stat. 728 (1902).
[13] 34 Stat. 768 (1906).
[14] *See* Hutt, *supra* note 10, at 428.
[15] 38 Stat. 785 (1914); *see* Hutt, *supra* note 10, at 428.
[16] *See* Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & Econ. 91, 91 (1979). Although it has been suggested that the manufacturer could limit a drug to prescription status, *see* Hutt, *supra* note 10, at 428, it does not seem like there was an effective mechanism to enforce this prior to 1938.
[17] 52 Stat. 1040 (1938); 21 U.S.C. §§ 301 *et seq.* (2006).
[18] Federal Food, Drug, and Cosmetic Act of June 25, 1938, Pub. L. No. 75-717 (1938), *reprinted in* Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of its legislative record 14 (1938) (current version at 21 U.S.C.

only category, "it did not say which drugs were to be sold by prescription or that some drugs could not be sold without one."[19] If anything, the FD&C Act's legislative history rejected the concept of a mandatory class of prescription drugs, instead emphasizing the right to self-medication. The report of the House of Representatives Committee on Interstate and Foreign Commerce, which recommended the bill to the House, said, "The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective."[20] Although the FD&C Act did somewhat limit the ability to self-medicate by keeping dangerous (non-narcotic) drugs off the market for the first time, people were left fully free to choose any non-dangerous, non-narcotic drug, and drugs that did happen to be sold by a prescription were only exempted from a few minor labeling requirements.[21]

FDA regulations promulgated shortly after the passage of the FD&C Act created the first general prescription-only category of drugs. Section 502(f) of the FD&C Act required drug labels to contain adequate directions for use and warnings against possible dangers from use, while at the same time obligating the Secretary of Agriculture to issue regulations exempting a drug or device from this requirement if "not necessary for the protection of the public health."[22] Pursuant to the Secretary's delegation of authority, the FDA issued regulations exempting a drug from the use and dangers labeling requirement if it contained a prescription-only warning, was shipped exclusively for use through a prescription, and included labeling for use that would not be understandable to a layperson.[23] If such a product was sold without a prescription, it was immedi-

§ 353(b) (2004)). Specifically, drugs dispensed on a prescription where exempted from the requirements of Section 502(b) (name and place of business of manufacturer, distributor, or packer and quantity of contents), Section 502(e) (common or usual name), and, under some circumstances, 502(d) (narcotics labeling). *Id.*

[19] TEMIN, *supra* note 8, at 47.

[20] H.R. Rep. No. 75-2139 (1938), *reprinted in* DUNN, *supra* note 18, at 822. FDA Chief Walter G. Campbell concurred in this assessment: "There is no issue... from the standpoint of the enforcement of the Food and Drugs Act about self-medication. This bill does not contemplate its prevention at all. If it did a single short section in the measure could have been drawn up to that effect. But what is desired... is to make self-medication safe." *Food, Drugs, and Cosmetics, Hearing on S. 1944 Before a Subcommittee of the Senate Committee on Commerce*, 73rd Cong. (1933) (statement of Mr. Walter G. Campbell, Chief of the Food and Drug Administration of the Department of Agriculture), *reprinted in* DUNN, *supra* note 18, at 1083.

[21] TEMIN, *supra* note 8, at 53.

[22] Food, Drug, and Cosmetic Act § 502(f), *reprinted in* DUNN, *supra* note 18, at 13.

[23] 3 Fed. Reg. 3168 (1938).

ately misbranded and the seller was liable for a violation of the Act.[24] Underlying this regulation was an assumption that directions for self-use could not be written for some drugs and a belief, reflecting the general attitude of the New Deal, that market protections were insufficient and regulatory protection of consumers was necessary.[25] Whereas Section 503(b) simply exempted a drug from limited labeling requirements if it was actually sold via a prescription, the 1938 regulations allowed manufacturers to create a prescription-only class of drugs simply by putting the appropriate warning on them and writing directions that could not be understandable to the ordinary person, thereby making distribution by a pharmacist without a prescription illegal and preventing self-medication.[26] Yet, even these regulations did not make prescription-only status mandatory for any drug or class of drugs; manufacturers were merely given an incentive, through the exemption from the onerous use and dangers labeling requirements, to create a prescription-only category.

The first truly mandatory general classification of drugs into prescription or nonprescription categories resulted from FDA regulations issued in 1944.[27] Under the 1938 regulations, the only test for determining whether a drug was prescription-only was whether the manufacturer chose to label it accordingly. Contrary to what might be expected, manufacturers labeled many drugs that were safe for self-medication as prescription-only because they were able to make higher profits with this limitation.[28] This practice both unduly restricted consumer access to safe and effective drugs and led to confusion among pharmacists and the public as to which products were safe for self-medication and which required supervision by a doctor.[29] Due to the confusion and undue restrictions, pharmacists sold many safe drugs that bore the prescription label with neither a prescription (in violation of the regulation) nor adequate directions and warnings for

[24] *See id.*

[25] Temin, *supra* note 8, at 49, 55.

[26] *See id.* at 47.

[27] Regulations promulgated in 1941 had changed the wording, but not the relevant substance, of the 1938 regulations. *See* 6 Fed. Reg. 1920 (1941).

[28] *See* Pray, *supra* note 8, at 133; Lance W. Rook, *Listening to Zantac: The Role of Nonprescription Drugs in Health Care Reform and the Federal Tax System*, 62 Tenn. L. Rev. 107, 126 n. 105 (1994).

[29] Pray, *supra* note 8, at 133.

self-use.[30] In response, the FDA amended the regulations in 1944 and specified a definition of a prescription-only drug as one that, "because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy, as safe and efficacious for use except by or under the supervision of a physician, dentist, or veterinarian."[31] This regulation created a mandatory class of nonprescription drugs—those that were generally recognized among experts as safe and effective for self-medication—for which the manufacturer was not exempted from labeling requirements and that, consequently, could not be limited to prescription-only sale.

In the late 1940s, as Congress took up what would become the Durham-Humphrey Amendments of 1951, a mandatory division between nonprescription and prescription drugs did exist by way of regulation. Drugs safe and effective for self-medication had to be labeled for nonprescription sale. For all other drugs, the manufacturer had a major incentive to limit them to prescription-only sale but was not required to do so. Although this distinction was mandatory, the determination as to whether a drug was safe and effective for self-medication was left to the manufacturer in the first instance, with the FDA limited to enforcement actions to insure compliance.

2.

An Overview of the Durham-Humphrey Amendment Process

On April 12, 1949, Congressman Carl T. Durham, Democrat of North Carolina, introduced a bill to amend Section 503(b) of the FD&C Act. This bill merely expanded the exemption in Section 503(b) to include all

[30] *See* Edward B. Williams, *Exemption from the Requirement of Adequate Directions for Use in the Labeling of Drugs,* 2 Food Drug Cosm. L.Q. 155, 159 (1947).

[31] 9 Fed. Reg. 12255 (1944); *see* Williams, *supra* note 30, at 159.

of the labeling requirements of Section 502.[32] When no action was taken on the bill during the first session of the 81^{st} Congress, Congressman Durham introduced a second bill to amend Section 503(b) on June 21, 1950. This created an exemption from most of the labeling requirements of Section 502, but limited the exemption to a drug dispensed by prescription that was: 1) habit-forming and subject to Section 502(d); 2) found by the Administrator of the Federal Security Agency,[33] after investigation and the opportunity for a public hearing, to be unsafe or ineffective for use without professional diagnosis or supervision; or 3) limited to use under professional supervision by its effective application under Section 505.[34] Senator Hubert Humphrey, Democrat of Minnesota, introduced a companion bill in the Senate containing the same language on June 29, 1950.[35] Neither bill made any headway.

Having failed twice in the 81^{st} Congress to amend Section 503(b), Congressman Durham tried a third time at the start of the 82^{nd} Congress, proposing H.R. 3298 on March 19, 1951.[36] Senator Humphrey introduced his companion bill, S. 1186, two days later.[37] Like the 1950 bills, they offered an exemption from labeling for drugs dispensed only on a prescription but this was limited to the same three classes of drugs as in 1950.[38] New to these versions (the "FDA discretion version") were provisions that: allowed interested parties to petition for a drug to be added to or removed from the Administrator's list of unsafe or ineffective drugs; provided for notice and comment on this petition; required a public hearing if an objection was made to the Administrator's decision; and allowed an appeal of the Administrator's decision to the court system.

[32] H.R. 4203, 81st Cong. (1949) *reprinted in* 11 FDA, A Legislative History of the Federal Food, Drug, and Cosmetics Act and Its Amendments 1-2 (1979).

[33] In 1951, the FDA was part of the Federal Security Agency, which also was responsible for programs such as social security. In 1953, the FSA was abolished and its functions transferred to the new Department of Health, Education, and Welfare. In 1980, the education portion was removed and the department was renamed the Department of Health and Human Services. The Federal Security Administrator in 1951 would be the equivalent today of the Secretary of HHS. However, since the Secretary delegates functions to the FDA, references to the "Administrator" in the legislative history for all practical purposes should be understood to refer today to the FDA Commissioner.

[34] H.R. 8904, 81st Cong. (1950), *reprinted in* FDA, *supra* note 32, at 4-6.

[35] S. 3852, 81st Cong. (1950), *reprinted in* FDA, *supra* note 32, at 9-11.

[36] H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 14-17.

[37] S. 1186, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 20-23.

[38] S. 1186, 82nd Cong. (1951); H.R. 3298, 82nd Cong. (1951), *both reprinted in* FDA, *supra* note 32, at 14-23.

The House Committee on Interstate and Foreign Commerce held hearings on H.R. 3298 ("House Hearings") from May 1-5, 1951.[39] The House Committee reported the bill favorably but significantly amended on July 16, 1951. Senator Humphrey had previously offered an amendment to his own bill on July 5, 1951 so that it would comport to the version reported out by the House Committee. [40] This version (the "scientific opinion version"), like its predecessors, exempted drugs dispensed on a prescription from most of the labeling requirements of Section 502. In addition, however, for the first time it required that certain drugs (besides narcotics) be dispensed only on a prescription. These drugs fell into three categories: 1) habit-forming drugs; 2) those drugs the Administrator determined, based on generally held expert scientific opinions, to be safe and effective only under professional supervision; and 3) drugs limited to use under professional supervision by their new drug applications (NDAs).[41] The scientific opinion version retained the provision that allowed petition by interested parties and required notice and comment, a public hearing on objection, and judicial review. But it also required that the public hearing be for the purpose of taking testimony from scientific experts.[42] During the House floor debate on this version, an amendment that eliminated the provision for determination by the Administrator was offered by Congressman Joseph P. O'Hara (the "O'Hara amendment") and approved.[43] The amended bill (the "enacted version") merely provided that a drug that was not safe for use because of the statutory standard described above could not be sold without a prescription.[44] Since the Administrator would no longer be making the Rx-OTC determination, the provisions for petition, notice and comment, public hearings, and judicial review were unnecessary and were eliminated. The amended bill passed the House on August 1, 1951.[45]

[39] *Hearings Before the Comm. on Interstate and Foreign Commerce, House of Representatives, Eighty-Second Congress, First Session, on H.R. 3298, A Bill to Amend Section 503(b) of the Federal Food, Drug, and Cosmetic Act* [hereinafter *"House Hearings"*], 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 27-229 (1979).
[40] *See* S. 1186, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 256-261.
[41] H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 264-272.
[42] *Id.*
[43] 97 Cong. Rec. 9340-9349 (1951), *reprinted in* FDA, *supra* note 32, at 343-352.
[44] H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 353-356.
[45] 97 Cong. Rec. 9349 (1951), *reprinted in* FDA, *supra* note 32, at 352.

The Senate then turned to the prescription drug issue. The Subcommittee on Health of the Committee on Labor and Public Welfare held hearings on S. 1186 and H.R. 3298 (as it passed the House) from September 11-13, 1951.[46] The Senate Committee recommended the bill favorably, though amending it so as to comport with the version that passed the House.[47] After very little debate, the Senate passed the amended bill on October 15, 1951.[48] The House and Senate agreed on minor differences at Conference and Public Law 215 of the 82^{nd} Congress, the Durham-Humphrey Amendments, became law on October 26, 1951.[49]

B.

The Legislative History of the Durham-Humphrey Amendments

1.

The "FDA discretion version"

The original version of the Durham-Humphrey Amendments introduced in the 82^{nd} Congress provided that:

> If the drug is intended for use by man and—(1) is a habit-forming drug subject to the regulations prescribed under section 502(d); or (2) has been found by the Administrator, after investigation and opportunity for a public hearing, to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law; or (3) if an effective application under section 505 limits it to use under the professional supervision of a practitioner licensed by law, such exemption shall apply only if such drug is dispensed upon a... prescription....[50]

Two important features of this version are worth noting. First, instead of creating a mandatory class of

[46] *Hearings Before the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate, Eighty-Second Congress, First Session, on S. 1186 and H.R. 3298, Bills to Amend Section 503(b) of the Federal Food, Drug, and Cosmetic Act of 1938, As Amended* [hereinafter *"Senate Hearings"*], 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 359-657.

[47] S. Rep. No. 82-946, at 1 (1951), *reprinted in* FDA, *supra* note 32, at 664.

[48] 97 Cong. Rec. 13127 (1951), *reprinted in* FDA, *supra* note 32, at 677.

[49] Durham-Humphrey Amendments of 1951, Pub. L. No. 82-215, 65 Stat. 648, *reprinted in* FDA, *supra* note 32, at 688-689.

prescription-only drugs, it merely provided an incentive, like the regulations it was replacing, by offering an exemption from labeling. Second, the first category, habit-forming drugs, and the third category, drugs limited to prescription by their NDAs, of the definition of prescription drugs were not controversial and passed into law essentially unchanged. It was the second category, drugs that are unsafe or ineffective without professional supervision, that was the focus of the Congressional debate. In this original version of the bill, the Administrator determined the safety and effectiveness of a drug and was expected to create a list of those drugs that could be sold only by a prescription.[51] Interested parties could petition for addition or removal from the list, which would force the Administrator to provide notice, allow comment, and hold a public hearing upon objection, but the final decision belonged to the Administrator, though subject to *de novo* review in a court of appeals.[52]

This original version of the Durham-Humphrey Amendments reflected the concerns of the pharmacy profession, which, in conjunction with the FDA, was the driving force behind the legislation.[53] Congressman Durham and Senator Humphrey were both pharmacists and the principal drafters of the bill included two representatives of major pharmacy associations.[54] Thus, as a general matter, the Congressional intent regarding this version reflected the desires and concerns of this profession. Congressman Durham, in his statement during the House Hearings, candidly admitted that the legislation was intended for the benefit of pharmacists, saying, "The purpose of the bill is to eliminate the detrimental confusion that exists at the present time and that handicaps the profession of pharmacy in its efforts to provide adequate service to the

[51] *See* S. 1186, 82nd Cong. 3-4 (1951); H.R. 3298, 82nd Cong. 3-4 (1951), *both reprinted in* FDA, *supra* note 32, at 14-23 (allowing interested parties to petition for drugs to be added or removed from "the list of drugs promulgated by the Administrator in accordance with clause (2) hereof"); *see also House Hearings*, 82nd Cong. 19 (1951) (statement of Hon. Oscar R. Ewing, Administrator, Federal Security Agency), *reprinted in* FDA, *supra* note 32, at 47 ("[T]he bill authorizes the Federal Security Administrator to list, by name, the drugs that are limited to prescription sale.").

[52] *See* S. 1186, 82nd Cong. 3-4 (1951); H.R. 3298, 82nd Cong. 3-4 (1951), *both reprinted in* FDA, *supra* note 32, at 14-23.

[53] *See* Charles Wesley Dunn, *The New Prescription Drug Law,* 6 Food Drug Cosm. L.J. 951, 963 (1951).

[54] The principle drafters of the bill were: 1) Herman S. Waller, counsel for the National Association of Retail Druggists; 2) Roy S. Warnack, a retail druggist active in the California Pharmaceutical Association, a group of retail pharmacists; 3) Charles Crawford of the FDA; and 4) Congressman Durham. *House Hearings*, 82nd Cong. 68 (1951), *reprinted in* FDA, *supra* note 32, at 95 (statement of Herman S. Waller, counsel for the National Association of Retail Druggists).

public."[55] The legislation offered the pharmacists three main benefits. First, it cleared up confusion about the requirements for prescription refills caused by a speech by FDA Commissioner Dr. Paul B. Dunbar to the National Association of Retail Druggists that compared a prescription to a canceled check, thereby forbidding all refills of prescriptions, regardless of the safety of the drug.[56] The bill permitted refills of drugs for which over-the-counter sale was allowed regardless of whether the prescribing physician had consented and prohibited refills of drugs restricted by the prescription legend without authorization of the prescriber.[57] Second, the bill authorized oral prescriptions and refill orders by doctors, rather than requiring a written order as under the current FDA interpretation.[58] These first two features of the bill proved uncontroversial and were enacted with only minimal discussion.

The third benefit the bill offered pharmacists, however, was the focus of extensive Congressional debate and is the focus of this legislative history. Beyond refills and oral prescriptions, the legislation offered pharmacists "a clear-cut method of distinguishing between 'prescription drugs'... and 'over-the-counter drugs'..., and [required] that drugs be so labeled as to indicate to the retail druggist and to the general public into which of these two classes they fall."[59] To achieve this, the bill replaced the existing system, where manufacturers interpreted the FDA regulations and decided whether to label a drug for prescription or OTC use, with a list of prescription drugs promulgated by the Administrator. The goal was to eliminate the lack of uniformity among manufacturers that plagued the current system and led to confusion and potential liability for

[55] *House Hearings*, 82nd Cong. 10 (1951), *reprinted in* FDA, *supra* note 32, at 38 (statement of Hon. Carl T. Durham, a Representative in Congress from the State of North Carolina).

[56] *See, e.g., id.*, at 38; *House Hearings*, 82nd Cong. 43 (1951), *reprinted in* FDA, *supra* note 32, at 70 (statement of Roy S. Warnack, Retail Druggist).

[57] *See House Hearings*, 82nd Cong. 11 (1951), *reprinted in* FDA, *supra* note 32, at 39 (statement of Hon. Carl T. Durham, a Representative in Congress from the State of North Carolina).

[58] *See, e.g., id.,* at 38-39; *House Hearings*, 82nd Cong. 42-43 (1951), *reprinted in* FDA, *supra* note 32, at 69-70 (statement of Roy S. Warnack, Retail Druggist) *House Hearings*, 82nd Cong. 62 (1951), *reprinted in* FDA, *supra* note 32, at 89 (statement of Herman S. Waller, Counsel for the National Association of Retail Druggists).

[59] H.R. Rep. No. 82-700, at 3 (1951), *reprinted in* FDA, *supra* note 32, at 277.

pharmacists.[60]

Although the reasons for the listing provision of the original version are quite clear, it is less obvious what factors the Administrator was supposed to consider in creating this list. The bill simply said that the Administrator would decide, after investigation and opportunity for a public hearing, whether a drug was unsafe or ineffective without professional supervision. How the Administrator would make this determination became a matter of concern at the House Hearings. Congressman Louis B. Heller, Democrat of New York, asked Oscar Ewing, Administrator of the Federal Security Agency, how it would be determined whether or not a drug could be sold without a prescription. Ewing responded, "It is just a matter of someone's judgment." Congressman Heller then asked, "And whose judgment would that be?," to which Ewing answered "That would be the Administrator's judgment after a hearing and the taking of evidence."[61] Later in the hearings, Congressman Charles A. Wolverton, Republican of New Jersey, inquired as to how the Administrator would determine what was a dangerous drug. Ewing responded, "I do not know what you can do but leave it to the good judgment of someone whom you believe would try to act fairly and honestly on the thing. . . ."[62] In response to continued inquiry from Congressman Wolverton, Ewing said, "[T]he main safeguard you have is the judgment and fairness of the Administrator. . . ."[63] Ewing forthrightly admitted that an Administrator even could put aspirin on the prescription-only list if he found it to be a dangerous drug at a hearing and the court of appeals upheld him, which would be likely as long as there was substantial evidence in the record supporting the Administrator.[64]

[60] *See id.*
[61] *House Hearings*, 82nd Cong. 24 (1951), *reprinted in* FDA, *supra* note 32, at 52 (statement of Hon. Oscar R. Ewing, Administrator, Federal Security Agency).
[62] *Id.* at 66.
[63] *Id.*
[64] *Id.*

Thus, in the first version of the Durham-Humphrey Amendments, the Rx-OTC decision was within the full discretion of the Administrator, though subject to *de novo* review by the court of appeals. Under this version, the Administrator could consider any factor he chose, both questions of science or medicine and broad questions of social harm, provided that he could marshal some evidence to support his decision. In effect, social policy was as equally valid a factor as anything else in the Rx-OTC determination.

It was precisely the broad discretion given to the Administrator in the FDA discretion version that led to its rejection. Although one powerful lobby, the pharmacists, had written this bill, another powerful lobby, the pharmaceutical companies, strongly opposed the discretion it gave the Administrator. To the famed food and drug lawyer Charles Wesley Dunn, representing the American Pharmaceutical Manufacturers' Association at the House Hearings, the problem with the proposed bill was that it substituted "a broad administrative definition of a prescription drug for the present objective one."[65] Dunn believed the discretion given to the Administrator was too vast and would have several negative consequences, including: the conversion of increasing numbers of old nonprescription drugs into prescription drugs and the resulting increase in medical costs, the undue interference with the medical profession's determination of the effectiveness of drugs, and the increase of bureaucratic control over the drug and medical industries leading to socialized medicine.[66] Other representatives of the pharmaceutical industry shared Dunn's opposition to the bill.[67] Although this opposition did not cause the House Committee to eliminate the Administrator's role in the Rx-OTC determination, it did lead them to limit the Administrator's power in making this decision.[68]

[65] *House Hearings*, 82nd Cong. 80 (1951), *reprinted in* FDA, *supra* note 32, at 106 (statement of Charles Wesley Dunn, representing American Pharmaceutical Manufacturers' Association).

[66] *Id.* at 108-111.

[67] *See, e.g., House Hearings*, 82nd Cong. 119 (1951), *reprinted in* FDA, *supra* note 32, at 145 (statement of Hugo H. Schaefer, Chairman, Committee on Legislation, American Pharmaceutical Association) ("[The bill] would give the Food and Drug Administration control over the conduct and policies of drug manufacturers as well as retail pharmacists, vastly beyond that required for preserving public health, welfare, and safety."); *House Hearings*, 82nd Cong. 194 (1951), *reprinted in* FDA, *supra* note 32, at 220 (statement of James F. Hoge, representing the Proprietary Association) ("The power to restrict any drug to prescription sale would coerce the manufacturer to submit to any labeling demand of the Government which had any semblance of support. No one can predict, sitting here today, the full extent of this power as it would take form and growth [sic] with each passing year.").

[68] There was also widespread objection to the provision for *de novo* review by the court of appeals because it was inconsistent with general standards of review of administrative actions, could raise Constitutional problems by allowing a court to make

2.

Version 2: The "Scientific Opinion Version"

The House Committee reported H.R. 3298 favorably, but significantly amended, to the full House. The significant amendments were to § 503(b), the provision most directly relevant to the Rx-OTC determination. The amended version read as follows:

> A drug intended for use by man which—(A) is a habit-forming drug to which section 502(d) applies; or (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, has been determined by the Administrator, on the basis of opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug (and, where a public hearing is required by paragraph (5), on the basis of evidence adduced at such hearing by such experts), to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug; or (C) is limited by an effective application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only... upon a... prescription.[69]

Perhaps the most important aspect of the scientific opinion version is that it introduced a prescription-only requirement for certain classes of drugs, rather than just creating an incentive for manufacturers to choose prescription-only status for their drugs. In addition, it abandoned the provision for *de novo* review in favor of the normal scope of judicial review provided by other sections of the FD&C Act, *de novo* review of questions of law and "substantial evidence" review of factual determinations.[70] However, for determining the role of social harms in the Rx-OTC decision, the provision of note is the added requirement that the Administrator base his

legislative judgments, and would cause problems for the courts of appeals who are not well-suited to hold trials of fact. *See, e.g., Housing Hearings*, 82nd Cong. 3 (1951), *reprinted in* FDA, *supra* note 32, at 31 (report of Federal Security Agency); *Housing Hearings*, 82nd Cong. 6 (1951), *reprinted in* FDA, *supra* note 32, at 34 (report of Justice Department); *Housing Hearings*, 82nd Cong. 7-9 (1951), *reprinted in* FDA, *supra* note 32, at 35-37 (report of Administrative Office of the United States Courts); *Housing Hearings*, 82nd Cong. 209-212 (1951), *reprinted in* FDA, *supra* note 32, at 235-238 (statement of Hon. Harold M. Stephens, Chief Judge, United States Court of Appeals for the District of Columbia).

[70]H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 271; H.R. Rep. No. 82-700, at 12 (1951), *reprinted in* FDA, *supra* note 32, at 286.

Rx-OTC decision on "opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug." Similarly, while retaining the provision allowing petitioning by interested parties and requiring a public hearing related to this petition, the revised version added a requirement that the public hearing be "for the taking of evidence of experts who are qualified by scientific training and experience to testify on the question of whether the drug in question is safe and efficacious for use only" with professional diagnosis and supervision.[71] No longer did the Administrator have unfettered discretion to consider any factor he chose in making his prescription/nonprescription determination; now, he had to consider the opinions of scientific experts.

The reason for this amendment is not difficult to decipher. In fact, the House Report acknowledged that the addition was meant as a compromise between the positions of the pharmacists (full discretion to the Administrator) and the pharmaceutical industry (no administrative determination). The Report said, "By incorporating this standard in the law and by specifying the process to be used by the Administrator in applying it, the committee believes it has achieved a practical and equitable solution of the dilemma in which it found itself as a result of the conflicting legislative recommendations submitted by the trade and professional organizations in the drug field."[72] The Committee sought to get the uniformity benefits of an administrative determination desired by the pharmacists while at the same time responding to the objections of the pharmaceutical industry by limiting the Administrator's role to "collecting informed medical opinions and... merely reflect[ing] the opinions generally held among medical experts."[73]

The true scope of the added language is not necessarily apparent on its face. First, the amendment could be read as merely requiring the Administrator to consider scientific opinions as one of many factors in the Rx-OTC determination. However, the proponents of this version of the bill clearly envisioned that

[71] H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 271.
[72] H.R. Rep. No. 82-700, at 11 (1951), *reprinted in* FDA, *supra* note 32, at 285.
[73] *Id.*

the Administrator would be *limited* to expert scientific opinion in making his determination. The House Report said, "In applying this standard to a given drug, the Administrator *is directed to follow* the opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of the drug in question."[74] Furthermore, in the event a hearing was demanded by an interested party, the House Report said, "At the hearing the evidence taken will be evidence presented by qualified experts. *The Administrator must base his action, after the hearing, on the testimony given by such experts, not on his own personal views.*"[75] Thus, the House Committee, which was the principal drafters of the scientific opinion version, believed that they were limiting the Administrator to merely collecting and reflecting expert medical opinions. Other proponents of the bill shared this view, including several Congressmen during the floor debate[76] and George P. Larrick, the Associate Commissioner of the Food and Drug Administration.[77] Thus, by giving the Administrator the power to promulgate a list of prescription drugs but limiting him to considering only expert scientific opinion, the scientific opinion version sought to "delegate this authority to the Administrator and then tie his hands so that he cannot abuse that authority."[78]

Second, the text only required the Administrator to base his decision, and take testimony at a hearing, on scientific *opinion*, rather than scientific *evidence*. From this, it reasonably could be concluded that the scientific experts were free to testify on questions of social harms, as well as scientific or medical harms,

[74] *Id.* (emphasis added).

[75] *Id.* (emphasis added).

[76] *See* 97 Cong. Rec. 9236 (1951), *reprinted in* FDA, *supra* note 32, at 316 (statement of Rep. Hugh B. Mitchell, D-WA) ("The purpose of the hearing would be to receive the testimony of experts qualified by scientific training and experience. . . .The Administrator *would be required to base* his decision solely on the evidence taken at the hearing. . . .") (emphasis added); 97 Cong. Rec. 9322 (1951), *reprinted in* FDA, *supra* note 32, at 325 (statement of Rep. Charles A. Wolverton, R-NJ) ("Twentieth Question: How is the power of the Administrator circumscribed and how are the rights of interested parties safeguarded? Answer: The Administrator is called upon to make his determination in accordance with a specific statutory standard defining dangerous drugs, and his determination *must be based* upon generally prevailing opinions of experts with respect to the safety of such drugs.") (emphasis added).

[77] *See Senate Hearings*, 82nd Cong. 13, *reprinted in* FDA, *supra* note 32, at 377 (statement of George P. Larrick, Deputy Commissioner of Food and Drugs, Food and Drug Administration, Federal Security Agency) ("The final decision of the Administrator *would be required to be based*, not on his own personal views but upon the opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of the drug when used without professional guidance.") (emphasis added).

[78] 97 Cong. Rec. 9333 (1951), *reprinted in* FDA, *supra* note 32, at 336 (statement of Rep. John Bell Williams, D-MS).

allowing the FDA to consider social harms that were generally recognized by scientific experts. However, the legislative history suggests that Congress wanted to limit the FDA to scientific opinions on scientific evidence. Charles Wesley Dunn, probably the foremost expert on FDA law at the time, clearly thought the scientific opinion version limited the FDA to such consideration.[79] More importantly, Senator Humphrey, a sponsor of the bill and a major supporter of the scientific opinion version, seems to have agreed with Dunn's interpretation.[80] Commonsense also suggests that Congress would not limit consideration to scientific opinion but then allow these opinions to be on topics, including social harms, about which the scientific experts would have no special knowledge.[81] Thus, Congress almost certainly intended the scientific opinion version to limit the Administrator to considering the generally accepted opinions of scientific experts on questions of science, not questions of social harm.[82]

[79] *See Senate Hearings*, 82nd Cong. 106 (1951), *reprinted in* FDA, *supra* note 32, at 469 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association) ("For while it was provided that his definition must be supported by *scientific evidence* and is subject to court review, he would have no difficulty in securing enough *scientific evidence* to support his definition in each instance despite the existence of other *scientific evidence* against it.") Since Dunn represented the pharmaceutical industry and was opposed to the scientific opinion version as giving the Administrator too much power, it is highly unlikely that he gave this version a narrower reading than was generally accepted in Congress.

[80] *See Senate Hearings*, 82nd Cong. 106 (1951), *reprinted in* FDA, *supra* note 32, at 469 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association):

Senator Humphrey: As I understand it, Mr. Dunn, the administrative regulation which the Food and Drug Administration has promulgated through the Administrator of the Federal Security Agency has been included in the House bill as a statutory provision.

Mr. Dunn: With two exceptions. The reference to efficacy was eliminated in the House.

Senator Humphrey: Yes.

Mr. Dunn: And also the reference to the necessity for supporting the classification by competent scientific evidence. Of course, this reference is implied, because you can't have a definition of a prescription drug, unless you have scientific evidence to support it.

Senator Humphrey: I would have assumed that.

[81] It was for the very reason that scientific experts had no special knowledge of efficacy that some members of Congress favored removing this term from the definition. *See* 97 Cong. Rec. 9335 (1951), *reprinted in* FDA, *supra* note 32, at 338 (statement of Rep. Fred L. Crawford, R-MI) ("Assuming that a man with great experience and scientific training did attempt to say that a drug was efficacious: On what ground can he do that? What scientific knowledge gives him the ability to say that a certain drug will cure my cold when my cold might be caused by something he knows nothing about?"). It could be argued that scientific experts, being intimately involved in the drug field, have special knowledge of the social problems that arise. However, by this logic, the FDA, as the agency responsible for regulating the drug field, would be more appropriate for making decisions based on social harms.

[82] *See also* 97 Cong. Rec. 9236 (1951), *reprinted in* FDA, *supra* note 32, at 316 (statement of Rep. Hugh B. Mitchell, D-WA) ("The expert testimony would deal with the question of *whether or not the drug could be safely used* without medical supervision including the question of whether or not the drug is one that the layman can use without medical supervision *as an effective weapon against his disease*.") (emphasis added); 97 Cong. Rec. 9322 (1951), *reprinted in* FDA, *supra* note 32, at 325 (statement of Rep. Charles A. Wolverton, R-NJ) ("[The Administrator's] determination must be based upon generally prevailing opinions of experts *with respect to the safety of such drugs*.") (emphasis added).

Despite these attempts to limit the power of the Administrator, the second version of the Durham-Humphrey Amendments was ultimately rejected because members of Congress believed that the provision for listing prescription drugs still gave the Administrator too much power, even if he was limited to considering scientific opinion. The pharmaceutical industry was highly skeptical that the scientific expert requirement would actually constrain the Administrator. Representatives of both the American Pharmaceutical Manufacturers' Association and the Proprietary Association asserted at the Senate Hearings that the Administrator would be able to find experts willing to support any decision he wanted to make.[83] Several House Members voiced this skepticism on the House floor,[84] leading in part to the elimination of this provision in the O'Hara Amendment.

More important to the rejection of the scientific opinion version than doubts about the objectiveness of scientific experts were doubts about Oscar R. Ewing. Ewing, as Administrator of the Federal Security Agency, the precursor to the Department of Health and Human Services, was President Truman's advocate for national health insurance.[85] As such, he was vilified by the medical and pharmaceutical industries as a proponent of socialized medicine,[86] a distrust that is reflected in the rejection of this version of the

[83] *See Senate Hearings*, 82nd Cong. 106 (1951), *reprinted in* FDA, *supra* note 32, at 469 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association) ("For while it was provided that his definition must be supported by scientific evidence and is subject to court review, he would have no difficulty in securing enough scientific evidence to support his definition in each instance despite the existence of other scientific evidence against it."); *Senate Hearings*, 82nd Cong. 146 (1951), *reprinted in* FDA, *supra* note 32, at 509 (statement of Dr. Frederick J. Cullen, Executive Vice President of the Proprietary Association of Washington, D.C.) ("It comes down to the point that the Administrator could select the particular experts who hold opinions that suit his purpose in a specific instance.") *Senate Hearings*, 82nd Cong. 149 (1951), *reprinted in* FDA, *supra* note 32, at 512 (supplemental statement of James F. Hoge, General Counsel, The Proprietary Association) ("The bill provides that the Administrator make his determination merely upon the basis of opinions of experts—selected, of course, by him and obtained from writings or ex parte examination.")

[84] *See, e.g.,* 97 CONG. REC. 9329 (1951), *reprinted in* FDA, *supra* note 32, at 332 (statement of Rep. John B. Bennett, R-MI) ("Everybody knows you can get medical experts to testify on both sides of any question. On the basis of the advice of his own medical experts, [the Administrator] can take a perfectly harmless drug or a drug that for years has been on the market and put it on the prescription list."); 97 CONG. REC. 9335 (1951), *reprinted in* FDA, *supra* note 32, at 338 (statement of Rep. Joseph P. O'Hara, R-MN) ("That means that you are giving to the Administrator the right to call in anybody; and he determines who is the expert, does he not?").

[85] J.R. Fuchs, *Oral History Interview with Oscar R. Ewing* (May 1, 1969), at http://www.trumanlibrary.org/oralhist/ewing3.htm.

[86] *Id.; see also* 97 CONG. REC. 9342, *reprinted in* FDA, *supra* note 32, at 345 (statement of Rep. Oren Harris, D-AR) ("It is a rather interesting thing when Oscar Ewing is being used as a whipping boy here. I will say to you if his name was not involved in this legislation you would not have a leg to stand on, and you know it. You drag out before this Committee the thing that you think will create the most prejudice against a good piece of legislation.").

Amendments. In introducing his amendment to eliminate the role of the Administrator in the Rx-OTC decision, Congressman Joseph P. O'Hara, Republican of Minnesota, said, "What is being attempted here is to give this terrific amount of power to Oscar Ewing and the Food and Drug Administration to bring about a complete change in the entire picture in this country. Let me say to you, and I say it in all seriousness, that this bill, at least as it is now written, is the handmaiden of socialized medicine."[87] Other Congressmen who supported the O'Hara Amendment concurred in these doubts about giving so much power to a person they saw as favoring socialized medicine.[88] Thus, the House Committee's version of the bill was rejected because it was seen as giving too much power to the Federal Security Administrator, a man not trusted by the members of Congress.[89]

3.

Version 3: The "Enacted Version"

[87] 97 CONG. REC. 9341 (1951), *reprinted in* FDA, *supra* note 32, at 344 (statement of Rep. Joseph P. O'Hara, R-MN).

[88] *See, e.g.,* 97 CONG. REC. 9237, *reprinted in* FDA, *supra* note 32, at 317 (statement of Rep. Leo Elwood Allen, R-IL) ("If this bill is not amended, Oscar Ewing will have the power under this bill to determine what drugs will be sold; and, if they are permitted to be sold, whether or not they will be sold over the counter or upon prescriptions. This is the same Oscar Ewing who is the original sponsor of socialized medicine. . . ."); 97 CONG. REC. 9325, *reprinted in* FDA, *supra* note 32, at 328 (statement of Rep. John V. Beamer, R-IN) ("Some more of the socialistic schemes are introduced in this manner by incorporating worthwhile legislation which we want to support with objectionable sections which we must oppose."); 97 CONG. REC. 9326, *reprinted in* FDA, *supra* note 32, at 329 (statement of Rep. Paul W. Shafer, R-MI) ("[T]his provision may easily become the handmaiden to socialized medicine. . . .[T]his provision gives the Federal Security Administrator opportunity increasingly to restrict the over-the-counter sale of drugs, thereby increasing cost of medication and creating one more artificial stimulus to the demand for socialized medicine.") 97 CONG. REC. 9327, *reprinted in* FDA, *supra* note 32, at 330 (statement of Rep. Clarence J. Brown, R-OH) (seeking an amendment that would give the pharmacists want they wanted but would "protect the medical profession from the threat of socialized medicine.").

[89] *See, e.g.*, 97 CONG. REC. 9237, *reprinted in* FDA, *supra* note 32, at 317 (statement of Rep. Leo Elwood Allen, R-IL) ("All opposition to this bill centers around the extraordinary powers proposed to be granted to Federal Security Administrator Oscar Ewing."); 97 CONG. REC. 9326, *reprinted in* FDA, *supra* note 32, at 329 (statement of Rep. Paul W. Shafer, R-MI) ("By conferring authority to determine the category in which each of some 30,000 drugs would be placed, we bestow on FSA, on Mr. Oscar Ewing, and on his successors as Federal Security Administrator, the power to legislate by directive."); 97 CONG. REC. 9327, *reprinted in* FDA, *supra* note 32, at 330 (statement of Rep. Joseph P. O'Hara, R-MN) ("I intend to offer an amendment which will strike out the objectionable features of this bill, namely, amending B and striking out subsection 5. That will remove this tremendous grant of administrative absolutism to Mr. Ewing as the Food and Drug Administrator, and I am sure a great many Members and many, many of the people of this country do not want him to have such power."); 97 CONG. REC. 9333, *reprinted in* FDA, *supra* note 32, at 336 (statement of Rep. George Meader, R-MI) (describing the House Committee version as "giving dictatorial power to the Federal Security Administrator"); *see also* S. REP. NO. 82-946, at 4 (1951), *reprinted in* FDA, *supra* note 32, at 667 ("The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing was not necessary at this time.").

The amendment suggested by Congressman O'Hara, and endorsed by the Senate Committee, was ultimately enacted into law as the Durham-Humphrey Amendments. Members of Congress viewed this version as removing the Rx-OTC determination from the control of the Administrator, though this was perhaps erroneous given the FDA's role in the approval of NDAs.[90] Instead, it provided a statutory standard based on the then-existing FDA regulations, requiring a drug to be dispensed only by a prescription if, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug."[91] The manufacturer would apply the statutory standard to determine whether a drug must be sold by a prescription only, subject to the possibility of an enforcement action by the FDA. The reason for this change was explored above and was principally a result of Congressional concern about giving too much power to Federal Security Administrator Oscar Ewing.

If the FDA discretion version of the bill reflected the desires and concerns of the pharmacy profession, the definition contained in the enacted version codified the desires and concerns of the pharmaceutical

[90]The enacted version did not completely remove the FDA from the initial decision since a drug could still be limited to prescription-only status in its NDA. According to FDA Deputy Commissioner George P. Larrick, the FDA could require a NDA to limit a drug to prescription-only status and often did so; this was frequently with the cooperation of the manufacturer but the FDA could require it over the objection of a manufacturer after a formal hearing and the opportunity for judicial review. *See Senate Hearings,* 82nd Cong. 14-16 (1951), *reprinted in* FDA, *supra* note 32, at 378-380 (statement of George P. Larrick, Deputy Commissioner of FDA). Despite the fact that the Durham-Humphrey Amendments explicitly preserved this role in the third prong of the prescription drug definition, members of Congress saw the move to the enacted version as leaving the initial decision to the manufacturer with the FDA limited to bringing enforcement actions if it disagreed with the decision. *See, e.g.,* 97 Cong. Rec. 9341 (1951), *reprinted in* FDA, *supra* note 32, at 344 (statement of Rep. Joseph P. O'Hara, R-MN) (noting that if different manufacturers took different views on whether a drug was prescription-only, the FDA could bring suit for mislabeling); 97 Cong. Rec. 9342 (1951), *reprinted in* FDA, *supra* note 32, at 345 (statement of Rep. Oren Harris, D-AR) ("You will leave to the authority of the commercial drug interests in this country to decide what is best for the American people and the health and welfare of the people."); 97 Cong. Rec. 9345 (1951), *reprinted in* FDA, *supra* note 32, at 348 (statement of Rep. John Bell Williams, D-MS) (noting that the scientific opinion version would allow the Administrator to decide if a drug should be prescription-only but if the O'Hara Amendment was adopted, the manufacturer would do so); 97 Cong. Rec. 9347 (1951), *reprinted in* FDA, *supra* note 32, at 350 (statement of Rep. Charles J. Kersten, R-WI) (favoring "the present system" where the Administrator did not decide what drugs must be prescription-only). The reason for this apparently erroneous view is unclear, but it likely had to do with Congressional misunderstanding about the role of the FDA in the NDA process or the belief that very few drugs would be limited to prescription-only status by their NDAs.

[91]H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 658-661.

industry.[92] Its ultimate acceptance resulted from a compromise between the pharmacy profession and the pharmaceutical industry reached during the Senate Hearings.[93] In exchange for the support of the pharmacy profession for their favored definition of a prescription drug, the pharmaceutical industry agreed to support two amendments favored by the pharmacists. The first narrowed the prohibition on improper labeling of nonprescription drugs with the prescription legend, and the second gave pharmacists who relied on a manufacturer's insufficient labeling a good faith defense from liability.[94] In light of this compromise, the Senate Committee recommended the House version of the bill with the suggested amendments and this version passed the Senate on October 15, 1951. The House agreed to the proposed amendments and the bill became law on October 26, 1951.

The enacted version of the bill essentially codified the 1944 FDA regulations.[95] The only major difference was that the bill only limited drugs that were unsafe without professional supervision to prescription-only status, whereas the regulations limited drugs that were unsafe or ineffective. However, the Senate Committee suggested that this was only a limited change, saying that it was "not intended to mean that the only matter to be considered in applying the definition is whether or not a particular drug is poisonous."[96]

III.

[92] *See* Dunn, *supra* note 53, at 963. In fact, the enacted version almost perfectly mirrored the suggestions of Charles Wesley Dunn in his testimony before the House Committee. *Compare House Hearings*, 82nd Cong. 79-85 (1951), *reprinted in* FDA, *supra* note 32, at 105-111 (statement of Charles Wesley Dunn, representing American Pharmaceutical Manufacturers' Association) *with* H.R. 3298, 82nd Cong. (1951), *reprinted in* FDA, *supra* note 32, at 658-661; *see also* Dunn, *supra*, at 955 (noting that final bill enacted Dunn's suggestions).

[93] *See* S. Rep. No. 82-946, at 2-3 (1951), *reprinted in* FDA, *supra* note 32, at 665-666 (noting Senate Committee favored definition of House bill because of agreement between National Association of Retail Druggists, the American Pharmaceutical Manufacturers' Association, the American Drug Manufacturers Association, and the Proprietary Association, which was not opposed by the Federal Security Agency).

[94] *Id.* at 7.

[95] *See id. at* 4 ("It is substantially the same as the administrative definition now contained in the regulations issued by the Federal Security Administrator under the provisions of the Federal Food, Drug, and Cosmetic Act."); 97 Cong. Rec. 9318 (1951), *reprinted in* FDA, *supra* note 32, at 351 (statement of Rep. John B. Bennett, R-MI) ("[T]he effect of the O'Hara amendment is relatively simple. What it does is to legalize the regulations under which the Food and Drug Administration has been operating in this field for a period of years.").

[96] S. Rep. No. 82-946, at 4 (1951), *reprinted in* FDA, *supra* note 32, at 667.

A.

Implications of Congressional Objectives for Consideration of Social Harms in the Rx-OTC Determination

Congress was presented with two relatively stark choices regarding social harms during the Durham-Humphrey Amendment process. The first version of the bill gave the Administrator complete discretion to make the decision, [97] allowing for full consideration of both scientific/medical harms and social harms, while the second version of the bill expressly limited the Administrator to consideration only of expert scientific testimony, thereby eliminating social harms as a valid consideration.[98] Unfortunately for purposes of determining the proper role of social harms, Congress chose neither of these alternatives, enacting instead a more ambiguous version. Although it could be argued that the rejection of the scientific opinion version on the House floor and in the Senate Committee reveals a Congressional intent for consideration of more than just science, this would misrepresent the legislative history. Congress rejected the scientific opinion version not because it thought that the decision-making was too constrained by this limitation but instead because it thought that the decision-making was not sufficiently constrained. Four broad Congressional goals motivated the move from earlier definitions of a prescription drug to that in the enacted version: to restrain the power of the Administrator, to enact the "objective" definition of the 1944 regulations, to preserve the right to self-medication, and to eliminate reference to the efficacy of a drug. Although there is no direct evidence in the legislative history as to whether or not Congress considered social harms to be an appropriate consideration for the Rx-OTC decision, each of these goals indirectly suggests that Congress intended the Rx-OTC determination to be limited to scientific considerations.

[97] *See* Section IIB, Part 1, *supra.*

[98] *See* Section IIB, Part 2, *supra.* Admittedly, the scientific opinion version on its face only limited the FDA to considering scientific opinion and did not address what the content of this opinion could be. However, the legislative history persuasively suggests that Congress intended to limit the FDA to consideration of expert scientific opinion on scientific evidence. *See id.*

1.

Restraining the Power of the Administrator

The legislative history of the Durham-Humphrey Amendments is a story of increasing restrictions on the power of the Administrator in the Rx-OTC determination. In the FDA discretion version, the Administrator was given full power and discretion over the decision. In the scientific opinion version, he was given the power to make the ultimate determination but had to base this determination solely on opinions generally held by scientific experts. Finally, in the enacted version, members of Congress intended the Administrator to have no role in the initial Rx-OTC determination and merely be able to bring enforcement actions if he disagreed with the manufacturer's classification. In light of these increasing restrictions and the opposition expressed by members of Congress to the Administrator and the power proposed to be given him in earlier versions of the bill,[99] it is clear that Congress wanted to give the Administrator as little power and discretion as possible. For that reason, it seems highly doubtful that Congress intended the FDA to consider broad questions of social harm. Such questions are inherently subjective, provide room for the exercise of discretion, and are not much narrower than the "judgment of the Administrator" standard rejected in the FDA discretion version. Thus, the very concerns that motivated Congress to reject both the FDA discretion version and the scientific opinion version—distrust of the Administrator and concern about giving him too much power and discretion—suggest that Congress did not view social harm as an acceptable consideration for the Rx-OTC determination.

That Congress permitted the provision allowing drugs to be limited to Rx-status in their NDAs to pass into law unchanged is an anomaly. This provision allowed the FDA to apply the statutory standard and limit a

[99] *See* Section IIB, part 2, *supra.*

drug to prescription-only status over the objection of the manufacturer by objecting to its OTC labeling.[100] This permitted the FDA to do at the NDA stage what it could not do once the drug was on the market and contradicts the expressed Congressional goal of limiting the Administrator's power. Although it is possible that Congress was only concerned about the power of the Administrator over existing drugs and accepted his broad power over new drugs, the vehement opposition to giving power to the Administrator suggests otherwise.[101] In fact, members of Congress were quite clear that they did not believe it was proper for the Administrator, or presumably the FDA, to decide whether a drug should be prescription-only,[102] which is essentially what would be allowed under the NDA provision. Perhaps acceptance of the NDA provision reflected a compromise between those favoring limited FDA powers and those favoring broad FDA powers, but this is highly unlikely given the lack of any evidence about such a compromise in the legislative history or even any discussion of this provision. Thus, the best conclusion that can be drawn is that the broad power the NDA provision gave the FDA was an oversight by Congress, either because they did not understand the FDA's role in the NDA process or did not understand that many drugs would be restricted to prescription-only status by their NDAs.

If Congress had anticipated a system where the FDA actually was making the primary Rx-OTC decision, it certainly would have wanted to limit its power and discretion. Limiting the Administrator to collecting and

[100] *See Senate Hearings,* 82nd Cong. 14-16 (1951), *reprinted in* FDA, *supra* note 32, at 378-380 (statement of George P. Larrick, Deputy Commissioner of FDA).

[101] *See, e.g.,* 97 CONG. REC. 9327, *reprinted in* FDA, *supra* note 32, at 330 (statement of Rep. Joseph P. O'Hara, R-MN) ("I intend to offer an amendment. . . .[t]hat will remove this tremendous grant of administrative absolutism to Mr. Ewing as the Food and Drug Administrator, and I am sure a great many Members and many, many of the people of this country do not want him to have such power."); 97 CONG. REC. 9333, *reprinted in* FDA, *supra* note 32, at 336 (statement of Rep. George Meader, R-MI) (describing the House Committee version as "giving dictatorial power to the Federal Security Administrator"); *see also* S. REP. NO. 82-946, at 4 (1951), *reprinted in* FDA, *supra* note 32, at 667 ("The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing was not necessary at this time.").

[102] *See, e.g.,* 97 CONG. REC. 9237, *reprinted in* FDA, *supra* note 32, at 317 (statement of Rep. Leo Elwood Allen, R-IL) ("If this bill is not amended, Oscar Ewing will have the power under this bill to determine what drugs will be sold; and, if they are permitted to be sold, whether or not they will be sold over the counter or upon prescriptions. . . ."); 97 CONG. REC. 9326, *reprinted in* FDA, *supra* note 32, at 329 (statement of Rep. Paul W. Shafer, R-MI) ("By conferring authority to determine the category in which each of some 30,000 drugs would be placed, we bestow on FSA, on Mr. Oscar Ewing, and on his successors as Federal Security Administrator, the power to legislate by directive.").

reflecting the generally accepted medical and scientific opinions of experts is an effective way to "delegate this authority to the Administrator and then tie his hands so that he cannot abuse that authority."[103] This approach, basically that of the scientific opinion version, was rejected on the House floor and in the Senate Committee as insufficiently restraining the Administrator's power.[104] However, knowing that it could not have its ideal solution of eliminating the role of the Administrator in the initial determination, Congress likely would have accepted limiting the Administrator to consideration of generally accepted scientific and medical harms as the second best way to achieve their foremost objective in choosing a definition of a prescription drug—limiting the power of the FDA.

2.

Enacting the "Objective" Definition of the 1944 Regulations

In lobbying in opposition to the first two versions of the bill, the pharmaceutical industry argued that they improperly substituted an "administrative definition" of prescription drugs, a definition dependent on action by the FDA, for the self-applying "objective definition" contained in the 1944 regulations.[105] This lobbying clearly worked, as both House members supporting the O'Hara Amendment[106] and the Senate Committee[107] saw the move from the scientific opinion version to the enacted version as codifying the 1944 regulations. To

[103] 97 Cong. Rec. 9333 (1951), *reprinted in* FDA, *supra* note 32, at 336 (statement of Rep. John Bell Williams, D-MS).
[104] *See* Part IIB, Section 2.
[105] *See, e.g., House Hearings,* 82nd Cong. 80, *reprinted in* FDA, *supra* note 32, at 106 (statement of Charles Wesley Dunn, representing American Pharmaceutical Manufacturers' Association) ("The objection is that it substitutes a broad administrative definition of a prescription drug for the present objective one. . . ."); *id.* at 107 ("This basic definition of a prescription drug [contained in the 1944 regulations] is clearly an appropriate and sound one; and consequently it is unnecessary to substitute another.").
[106] *See, e.g.,* 97 Cong. Rec. 9348, *reprinted in* FDA, *supra* note 32, at 351 (statement of Rep. John B. Bennett, R-MI) ("[T]he effect of the O'Hara amendment is relatively simple. What it does is to legalize the regulations under which the Food and Drug Administration has been operating in this field for a period of years.")
[107] S. Rep. No. 82-946, at 4 (1951), *reprinted in* FDA, *supra* note 32, at 667 ("It is substantially the same as the administrative definition now contained in the regulations issued by the Federal Security Administrator under the provisions of the Federal Food, Drug, and Cosmetic Act.")

the extent that this definition was actually "objective" as claimed by the pharmaceutical industry, it would seem to preclude consideration of social harms, since social issues are inherently subjective. Obviously, the definition of a prescription drug contained in the regulations, and adopted by the Durham-Humphrey Amendments is not facially objective; neither "other potentialities for harmful effect" nor "collateral measures necessary to its use" are clear and both leave plenty of room for reasonable minds to disagree.[108] However, since the basic purpose of the Durham-Humphrey Amendments was to eliminate confusion and inconsistency that plagued the pharmacy profession,[109] Congress likely wanted to limit manufacturers to consideration of the generally accepted scientific and medical opinions of experts in applying the definition of a prescription drug. If consideration of social harms were allowed, the Rx-OTC determinations of different manufacturers would likely differ for the same or similar products based on differing views of social policy. This was the exact situation that motivated introduction of the Durham-Humphrey bill in the first place. On the other hand, manufacturers are much more likely to have the same view as to the generally accepted opinions of experts on scientific and medical issues. Thus, while limiting consideration to scientific questions would not achieve the perfect consistency desired by the pharmacy profession, it would come a lot closer than allowing consideration of social harms and as a result better represents Congressional intent.

Furthermore, the repeated reference in the legislative history to enacting the 1944 regulations into statute supports the view that only science, and not social policy, was to be considered in making the Rx-OTC determination. The 1944 regulations provided that a drug was exempted from the relevant labeling requirements if:

[108]The meaning of the terms of the definition and their role in determining whether social harms are appropriate Rx-OTC switch considerations is considered in more detail *infra*, Part IIIB.
[109]*See* Part IIB, Section 1.

> Such drug or device, because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use, is not generally recognized *among experts qualified by scientific training and experience to evaluate its safety and efficacy*, as safe and efficacious for use except by or under the supervision of a physician. . . .[110]

The reference in the regulations to scientific experts limited the decision to scientific and medical evidence.[111] Thus, by seeking to enact these regulations into statute, Congress seemed to endorse a science-only determination. Although elimination of the reference to scientific experts when the 1944 regulations were codified in 1951 could be seen as broadening the permissible considerations, two factors suggest otherwise. First, there is no suggestion by any member of Congress of an intent to depart from the science-only definition of the 1944 regulations and, to the contrary, there is a plethora of explicit statements of a desire to enact the 1944 regulations into statute. Second, such a reading would conflict with the efforts of the pharmaceutical companies to achieve an objective definition discussed in the preceding paragraph. Since the definition in the enacted version reflected exactly what Charles Wesley Dunn had advocated for on behalf of the pharmaceutical industry,[112] it is implausible that Congress would deviate from the desires of this industry only on the limitation to scientific experts issue without there being some mention of this in the legislative record. Instead, the exclusion of this language is probably better explained by a desire to distinguish the proposed O'Hara amendment from the scientific opinion version that was being considered at the time, which contained references to the opinions of scientific experts. Exclusion of the reference to scientific experts may also be explained by Congressional acceptance of Dunn's argument that the definition was inherently limited to scientific considerations regardless of reference to scientific opinions. Dunn told the House Committee, "For the existing definition [the regulatory definition] is a generic and scientific one, which is fully protective in the circumstances. . . "[113] and told the Senate Committee, "[T]his reference [to requiring scientific evidence

[111] On its face, the regulation does not prevent these experts from opining on social issues. However, as discussed *supra*, it is likely that when the FDA and Congress referred to reliance on scientific experts, they intended this to mean reliance on the scientific opinions of scientific experts. *See supra,* Part IIIA, Section 2.

[112] *See House Hearings,* 82nd Cong. 79-85 (1951), *reprinted in* FDA, *supra* note 32, at 105-111 (statement of Charles Wesley Dunn, representing American Pharmaceutical Manufacturers' Association).

[113] *House Hearings,* 82nd Cong. 81 (1951), *reprinted in* FDA, *supra* note 32, at 107 (statement of Charles Wesley Dunn,

to support classification] is implied, because you can't make a definition of prescription drug, unless you have scientific evidence."[114]

The definition of a prescription drug that was ultimately enacted into law reflected the desires of the pharmaceutical industry and their supporters in Congress to enact the "objective" definition of the 1944 regulations, rather than the administrative definition proposed in earlier versions. The best conclusion that can be drawn from this successful effort is that Congress intended to limit the Rx-OTC decision to considerations of scientific expert evidence.

3.

Preserving the Right of Self-Medication

Commentators agree that the Durham-Humphrey Amendments, like the 1938 FD&C Act, sought to protect and improve the right to self-medication by not unduly restricting access to any safe nonprescription drug.[115] This view is well supported by the legislative record. Trying to assuage fears of House members regarding the FDA discretion version, FDA Associate Commissioner Larrick said, "Our thinking is that considering the legislative history of the Food, Drug, and Cosmetic Act, and the many references in this statute to the fact that the Congress does not wish to outlaw self-medication, but does want to make self-medication safe and effective, that we, in making this list, should always bear in mind that the Congress has instructed us not to unnecessarily restrict self-medication."[116] Similarly, in his mock question and answer on the House

representing American Pharmaceutical Manufacturers' Association).

[114] *Senate Hearings,* 82nd Cong. 110 (1951), *reprinted in* FDA, *supra* note 32, at 473 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association). That members of Congress agreed with Mr. Dunn's interpretation is revealed by Senator Humphrey's response to Mr. Dunn's assertion that the enacted definition implicitly limited consideration to scientific evidence. Senator Humphrey said, "I would have assumed that." *Id.*

[115] *See* Hutt, *supra* note 10, at 432; *see also* United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 478 (E.D. Mich. 1967).

[116] *Housing Hearings,* 82nd Cong. 110 (1951), *reprinted in* FDA, *supra* note 32, at 136 (statement of George P. Larrick, Associate Commissioner of Food and Drugs, Food and Drug Administration, Federal Security Agency).

floor, Congressman Wolverton assured House members that the scientific opinion version would improve, not undermine, self-medication.[117] Finally, those advocating the enacted version claimed that it did a better job of protecting the right of self-medication than the prior versions.[118] While there may not have been agreement as to which version of the Durham-Humphrey Amendments was best, there was general agreement that the right to self-medication should be protected and improved.

This Congressional goal is reinforced by the oft-asserted desire to enact the 1944 regulations into statute.[119] Some leading commentators have suggested that the post-1938 regulations by the FDA reflected a break with the Congressional desire to preserve self-medication.[120] Although this may be true of the initial regulations issued in 1938, the 1944 regulations actually represented a move in favor of self-medication. The motivation for those changes was a concern that manufacturers were unnecessarily labeling safe drugs for prescription-only sale.[121] The FDA's real concern was probably that drugs were being sold with neither labeling for self-use nor a prescription, but the effect of the 1944 changes was to promote self-medication by insuring that all drugs generally recognized as safe and effective for self-medication were available. Thus, to the extent that Congress sought to enact the 1944 regulations into law, it enacted a definition that promoted safe self-medication.

[117] 97 CONG. REC. 9323 (1951), *reprinted in* FDA, *supra* note 32, at 326 (statement of Rep. Charles A. Wolverton, R-NJ) ("Thirty-fourth question: Does the bill restrict the public's choice of remedies? Answer: No. It guarantees that all drugs that can be safely used by a layman shall be labeled with complete directions which the purchaser can follow without medical advice. It does prevent the sale without a prescription of drugs that would harm the purchaser if he took them without professional advice. It is distinctly advantageous to the public."). The minority report of the House Committee disagreed with this assessment, claiming that "there is no doubt that the bill as reported jeopardizes the traditional right of self-medication and choice of remedies." H.R. Rep. No. 82-700, at 31 (Minority Report), *reprinted in* FDA, *supra* note 32, at 305. The minority believed that taking the decision away from the Administrator—which is what eventually occurred—would better protect the right of self-medication.

[118] *See, e.g.*, *Senate Hearings*, 82nd Cong. 140 (1951) (statement of Dr. Frederick J. Cullen, Executive Vice President of the Proprietary Association of Washington, D.C.) ("If [the scientific opinion version] is enacted in its present form. . . [w]e are sure that in a very short time many of the products that are now being used in self-medication will be placed upon the prescription list, and as the years go on the list of drugs that may be used for self-medication will be reduced until proprietary remedies will practically disappear from the market.")

[119] *See supra,* Part IIIA, Section 2.

[120] *See* TEMIN, *supra* note 8, at 53-55; Williams, supra note 30, at 164-167.

[121] *See supra,* Part IIA, Section 1.

Although the Congressional desire to promote self-medication is itself a decision of social policy, it actually supports the conclusion that Congress did not intend social harms to be part of the Rx-OTC determination. When Congress was legislating in 1951, as in 1938, it made the social policy decision that most non-narcotic drugs should be available to consumers without a prescription. The only change between 1938 and 1951 was the addition of a relatively narrow exception for those drugs that were not safe and effective for self-medication. In the Durham-Humphrey Amendments, Congress construed this exception even more narrowly by eliminating reference to effectiveness.[122] Thus, in creating a class of mandatory prescription drugs, Congress made a determination of social policy that access to drugs should only be restricted when absolutely necessary: when the drug was unsafe, due to actual harmful consequences, for self-medication.[123] With the exception of these harmful drugs, Congress implicitly determined that consumers themselves, and the market as a whole, should weigh other considerations—e.g. price, morality, social harms, etc.—and determine whether the benefits of the drug outweighed its downsides. Consideration of social harms in the Rx-OTC decision would allow the FDA, rather than consumers and the market, to weigh the benefits of drugs against their social harms and would prevent consumer access to drugs that would not directly harm them. Thus, FDA consideration of social issues would exceed the authority given to the FDA in 1951 because Congress had already determined that self-medication outweighed any other factors, including social harms, that did not pose an immediate risk to the safety of the consumer.

4.

Eliminating Reference to Effectiveness

[122] *See infra,* Part IIIA, Section 4.

[123] *See* United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 480 (E.D. Mich. 1967) (["I]t seems that the Government, in order to prevail in this case, must establish that Decholin has a potentiality for causing consequences for an unadvised layman which can actually be called harmful; for in common usage the term 'safe' is not inapplicable to an article merely because the product may give rise to some effects which are uncomfortable or cause some inconvenience."); *see also infra*, Part IIIB, Section 3.

The only change in the Durham-Humphrey Amendments from the 1944 definition that Congress considered important was elimination of the reference to effectiveness.[124] Under the 1944 regulations, a drug was appropriate for prescription-only status if it was "safe and efficacious for use under the supervision of a physician,"[125] whereas the Durham-Humphrey Amendments limited prescription drugs to those "not safe for use except under the supervision of a" licensed practitioner.[126] Although limitation of the definition to unsafe drugs was not meant to suggest that the only relevant consideration was the inherent toxicity of a drug,[127] it was meant to narrow the allowable considerations in making the Rx-OTC decision.[128] Proponents of the elimination of efficacy saw it as promoting, at least in part, the Congressional goals of restraining the power of the Administrator,[129] enacting the "objective" definition of the 1944 regulations,[130] and promoting the right to self-medication.[131]

[124] *See* S. Rep. No. 82-946, at 4, *reprinted in* FDA, *supra* note 32, at 667; *see also Senate Hearings*, 82nd Cong. 110 (1951), *reprinted in* FDA, *supra* note 32, at 473 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association).

[125] 9 Fed. Reg. 12255 (1944).

[126] Durham-Humphrey Amendments of 1951, Pub. L. No. 82-215, *reprinted in* FDA, *supra* note 32, at 688.

[127] *See* S. Rep. No. 82-946, at 4, *reprinted in* FDA, *supra* note 32, at 667.

[128] *See, e.g.* H.R. Rep. No. 82-700, at 30 ("Minority Report"), *reprinted in* FDA, *supra* note 32, at 304 (favoring elimination of efficacy because "[t]his control [by the Administrator] is widened by the use of the words 'efficacy' and 'efficacious"'); 97 Cong. Rec. 9334 (1951), *reprinted in* FDA, *supra* note 32, at 337 (statement of Rep. Kenneth A. Roberts, D-AL) (proposing amendment on House floor, as member of the House Committee who supported the scientific opinion version, to eliminate reference to efficacy as being "too broad").

[129] *See, e.g.,* 97 Cong. Rec. 9334 (1951), *reprinted in* FDA, *supra* note 32, at 337 (statement of Rep. John Bell Williams, D-MS) ("I feel that this amendment [removing reference to efficacy] eliminates the dangers which are anticipated in this bill by the gentleman from Minnesota [Congressman O'Hara], that is, the granting to the Federal Security Administrator of improper or unwarranted authority."); 97 Cong. Rec. 9335 (1951), *reprinted in* FDA, *supra* note 32, at 338 (statement of Rep. John B. Bennett, R-MI) (supporting elimination of efficacy "because it gives too much authority to the Federal Security Administrator.").

[130] *See, e.g.,* 97 Cong. Rec. 9335 (1951), *reprinted in* FDA, *supra* note 32, at 338 (statement of Rep. Fred L. Crawford, R-MI) ("Assuming that a man with great experience and scientific training did attempt to say that a drug was efficacious: On what ground can he do that? What scientific knowledge gives him the ability to say that a certain drug will cure my cold when my cold might be caused by something he knows nothing about?"); *see also House Hearings,* 82nd Cong. 163 (1951), *reprinted in* FDA, *supra* note 32, at 189 (statement of Leslie D. Harrop, General Counsel, American Drug Manufacturers Association) ("When you talk about efficacy, there are bound to be differences [among scientific experts]. You can get the finest experts in the country, and half of them will line up on one side and half on the other side.").

[131] *See, e.g. House Hearings,* 82nd Cong. 194 (1951), *reprinted in* FDA, *supra* note 32, at 220 (statement of James F. Hoge, representing the Proprietary Association) ("[T]he inclusion of the word 'ineffective'. . . .jeopardizes the traditional right of self-medication and choice of remedies."); *Senate Hearings*, 82nd Cong. 140 (1951), *reprinted in* FDA, *supra* note 32, at 503 (statement of Dr. Frederick J. Cullen, Executive Vice President of the Proprietary Association of Washington, D.C.) ("But efficacy is based upon opinion, and to include the word "efficacious" in a law such as this world [sic—would] be to open the door to an almost unlimited control of therapeutics. The Administrator could jeopardize the traditional right of self-medication and the choice of remedies for minor ills.")

The elimination of reference to efficacy is not directly related to the consideration of social harms. However, through this action, Congress sought to narrow the permissible issues in the Rx-OTC switch as much as possible, a goal that conflicts with the consideration of social harms, which are far broader and less definite a criteria than effectiveness.

B.

Relationship Between the Specific Provisions of the Definition and the Consideration of Social Harms in Making the Rx-OTC Determination

Having concluded from the broad Congressional objectives behind the Durham-Humphrey Amendments' choice of definition that social harms were not intended considerations in the Rx-OTC decision, the specific provisions of the definition must still be considered to determine whether they shed any light on the role of social harms. Although the legislative record is sparse as to any discussion of the meaning of these terms, it is quite clear that the only terms that leave room for consideration of social policy are "other potentialities for harmful effect" and "collateral measures necessary to its use." However, the appropriateness of considering of social policy under these terms is questionable, especially given the requirement that any consideration affect the safety of the drug.

1.

Toxicity/Method of Use

There is general agreement that neither toxicity nor method of use allow for consideration of social harms.

Toxicity, as used in this provision, has been variously defined to mean "poisonous";[132] to mean "the state of being a potential source of harm for any reason directly attributable to its ingredients";[133] and to mean "[d]rugs that have a low margin of safety, and which must therefore be titrated carefully to achieve an adequate level of effectiveness without endangering patient safety."[134] Furthermore, toxicity was the only one of the four prongs of the definition explained in the legislative record. In testimony before the Senate Committee, Charles Wesley Dunn, perhaps the chief proponent of the enacted definition, said, "Now [toxicity] is a purely scientific question, which is first decided in the laboratory, and secondly, is determined by clinical experience on a control basis."[135] Given the purely scientific nature of the toxicity inquiry, it allows no room for social harms.

Unlike toxicity, the legislative record is bare as to the meaning of "method of use." However, by its text, this prong seems to refer to how the drug is administered (e.g. orally, by injection, etc.) and to limit consideration to whether a doctor is needed to supervise administration of the drug and to monitor the patient's progress on the drug.[136]

2.

Other Potentialities for Harmful Effect/Collateral Measures Necessary to Its Use

Discussion of the meaning of "other potentialities for harmful effect" is lacking in the legislative record, and

[132] *See* 97 Cong. Rec. 9335 (1951), *reprinted in* FDA, *supra* note 32, at 338 (statement of Rep. Oren Harris, D-AR) (equating toxic to poisonous).
[133] United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 476 n. 2 (E.D. Mich. 1967).
[134] Hutt, *supra* note 10, at 433.
[135] *Senate Hearings*, 82nd Cong. 112 (1951), *reprinted in* FDA, *supra* note 32, at 475 (statement of Charles Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers' Association).
[136] *See* Hutt, *supra* note 10, at 437. Hutt questions the importance of this factor today given that most drugs can be self-administered; for example, insulin is administered by injection but is available without a prescription. *Id.*

its textual meaning is unclear. It could be argued that the toxicity prong was meant to cover scientific and medical harms and that the "other potentialities" prong was meant to cover all other types of harm, including social harms. On the other hand, the prong's textual juxtaposition next to "toxicity"[137] and the fact that none of the definitions of toxicity cover all possible scientific or medical harms could mean that "other potentialities" was meant to cover those scientific or medical harms not included within the chosen definition of toxicity (i.e. those that do not result directly from the drug's ingredients). One court considering this provision concluded that it was broader than toxicity but still limited to concerns regarding human health.[138] A leading commentator has implicitly endorsed this view. He read this phrase to include potential for abuse, serious or common harmful effects from interaction with other products, and the development of a harmful tolerance,[139] all of which can be viewed as medical or scientific harms because of their effects on the human body.[140] On the other hand, he argued that this provision did not include the potential for tampering with OTC products or the possibility for use as an ingredient in creating narcotics,[141] both of which are more akin to social harms because they relate to human behavior.

Likewise, there is a complete dearth of Congressional discussion of the phrase "collateral measures necessary to use" and its textual meaning is also far from clear. The ambiguity and potential breadth of this term has led one leading commentator to argue persuasively that this provision was intended "to have the broadest

[137]The use of "and" between "toxicity" and "other potentialities for harmful effect" seems to suggest that these form a single prong of a three-prong definition (rather than two parts of a four-prong definition). Though often considered separately, this textual reading provides support for the assertion that "other potentialities for harmful effect" is limited to scientific and medical considerations in the same way as toxicity.

[138]National Nutritional Foods Ass'n v. Weinberger, 366 F.Supp. 1341, 1346 (S.D.N.Y. 1973) ("It is plain that the concern over 'potentiality for harmful effect' imposes broad responsibility on the Commissioner to safeguard human health."), aff'd by 491 F.2d 845 (2nd Cir. 1973). The court, consistent with the interpretation of Hutt, *see infra* note 118, concluded that it was appropriate for the FDA to limit sale of a vitamin to a prescription based on concerns that people would use excessive dosages. *See National Nutritional Foods Ass'n*, *supra.*

[139]Hutt, *supra* note 10, at 435.

[140]Admittedly, the potential for abuse could be viewed as a social harm. However, the commentator seems to be referring to the addictiveness of the drug, for he says that a drug listed under the Controlled Substances Act would be denied OTC status under this provision. *Id.* Addictiveness relates to the drug's effect on the body and is therefore a scientific consideration.

[141]*See id.* at 436.

possible scope" and to "encompass[] all aspects of the circumstances under which a drug is used, including broad questions of social policy," such as issues of morality, the need to have cheap and easily available drugs, the cost of medical care, protection of the medical and pharmacy professions, and the profitability (and consequential incentive to research) of the pharmaceutical industry.[142] Though perhaps not going as far as the distinguished commentator, one court considering the definition in detail also gave a relatively broad reading to "collateral measures necessary to its use." Rejecting the assertion that Congress' elimination of express reference to effectiveness prevented it from being considered under this prong, the court said that the ineffectiveness of a drug could be considered under the collateral measures heading to the extent that it made the drug unsafe—for example, because it would mask symptoms without curing the problem so as to prevent a person from knowing that medical advice was needed.[143]

Although the collateral measures provision was certainly intended to allow consideration of a broader range of issues than the preceding terms, it is far from clear that social harms were meant to be included. In fact, definitions of collateral measures offered by both the FDA and the Justice Department have excluded consideration of social harms. In a 1985 article, the then-director of the FDA's Office of Drug Standards asserted that three questions were considered in evaluating a drug under the "method of use" and "collateral measures" prongs: 1) can the disease be self-diagnosed?; 2) are the symptoms self-recognizable?; and 3) can the condition be self treated?[144] Similarly, in a litigation alleging a violation of Section 503(b)(1)(B), the Justice Department said that collateral measures necessary to safe use mean:

[142] *Id.* at 436, 438-439.
[143] United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 481-483 (E.D. Mich. 1967).
[144] Peter H. Rheinstein, *Criteria Used by the FDA to Determine What Classes of Drugs Are Appropriate Switch Candidates*, 19 Drug Info. J. 139, 141 (1985).

> all those things which a layman, because of his or her lack of education, training, and experience, cannot do to safely manage the disease. These include taking a proper history, doing a physical exam, ordering appropriate laboratory tests, having a knowledge of the disease that cause [the condition], integrating the results of the history, exam, and tests with this knowledge, making a diagnosis, designing a treatment plan, and carrying the plan through with proper continuing evaluation.[145]

Both of these definitions give broad scope to the "collateral measures" prong, as urged by the Senate Report, allowing for a wide variety of considerations beyond the mere toxicity or other inherent characteristics of the drug.[146] Yet, both are limited to scientific or medical considerations and do not envision a role for social harms.

Although arguments can be made that both the "other potentialities" and "collateral measures" prongs were meant to include consideration of social harms, it is probably better to view both of these prongs as ambiguous on the issue.

3.

Safety

Even if the "other potentialities" or "collateral measures" prongs were broad enough to allow consideration of social harms, such consideration would still be limited by the requirement of relationship to the safety of the drug. The Senate Report makes this clear in using the phrase "the collateral measures necessary to [a drug's] *safe* use."[147] Similarly, the court in *United States v. An Article of Drug... "Decholin"* noted that its discussion of the Congressional intent behind the word "safety" in relation to the toxicity prong was equally applicable to the collateral measures prong.[148] Based on this, the court rejected the argument

[146] *See* S. Rep. No. 82-946, at 4 (1951), *reprinted in* FDA, *supra* note 32, at 667.
[147] S. Rep. No. 82-946, at 9 (1951), *reprinted in* FDA, *supra* note 32, at 672.
[148] *Decholin*, 264 F. Supp. at 484. Although the safety requirement has not been directly applied to "other potentialities for harmful effect," there is no good reason to apply it to two of the prongs but not the others.

that effectiveness could generally be considered under the "collateral measures" prong, instead limiting consideration of effectiveness to the extent that it related to the drug's safety.[149] For social harms to be considered under the "other potentialities" or "collateral measures" prong consistent with the legislative history, there would similarly have to be an impact on the safety of the drug. Thus, an inquiry into the meaning of the term "safety" in Section 503(b)(1)(B) is necessary.

The Senate Report is clear that "'safe,' as used in the definition, is intended to have its ordinary meaning."[150] Less clear is what exactly this ordinary meaning is. The Senate Report said that toxicity, whether or not the drug is poisonous, is "only one factor to be considered by courts in determining whether a particular drug is safe for use without medical supervision" and that courts must also consider the other elements of the definition: other potentiality for harmful effects, the method of use, and collateral measures necessary for use.[151] Furthermore, the Senate Report noted that this was a broad definition meant to protect the public health by covering all drugs that required medical supervision in order to insure their safety.[152] From this evidence, one leading commentator has concluded that "Congress intended a broad range of inquiry in determining the prescription/nonprescription status of a drug" and that safety was intended to include "any threat to the public health."[153] Since certain social harms are threats to the public health, they would be appropriate considerations under this view.

Although it is certainly true that Congress intended a broad definition of safety, it is questionable whether this definition was meant to include social harms.[154] The inquiry is still limited to the ordinary definition of "unsafe." Thus, the *Decholin* court concluded that the definition of safety limited consideration in two

[149] *Id.* at 481-483.
[150] S. Rep. No. 82-946 (1951), at 4, *reprinted in* FDA, *supra* note 32, at 667.
[151] *Id.*
[152] *Id.* at 4, 9.
[153] Hutt, *supra* note 10, at 433.
[154] *See id.* at 436 (suggesting that "[t]here is perhaps no issue involving drug use that cannot properly be brought into consideration under [the method of use and collateral measures necessary for use] factor").

ways. First, the potential consequences of the drug must actually be *harmful* not merely, for example, uncomfortable or inconvenient.[155] Second, there must be a realistic probability, not just the mere possibility, of this actual harm when the drug is used appropriately.[156] The Senate Report provides some guidance as to what was meant by "harmful" by giving two examples of non-toxic drugs that were unsafe because "unsupervised use may indirectly cause injury or death."[157] This example suggests that Congress was thinking about effects on the body (i.e. scientific or medical harms) and not effects on behavior (i.e. social harms) in enacting the safety requirement. To the extent this is true, the definition of safety would exclude social harms.

4.

Summary

Relatively good arguments can be made that two of the provisions of the statutory definition—"other potentialities for harmful effect" and "collateral measures necessary to its use"—open the door to consideration of social harms. On the other hand, commentators and the Government have interpreted these phrases as relating to effects on the body, not effects on behavior. Furthermore, even if social harms could be considered under these prongs, all factors in the Rx-OTC determination must affect the safety of the drug, which Congress seemed to limit to effects on the body, such as injury or death. Thus, social harms, which are effects on behavior, normally would not satisfy the safety requirement. Even if they did cause indirect effects to the human body, such as the failure to treat a disease due to the high cost of medical care, they likely would not satisfy the requirement that there be reasonable probability, not just a theoretical possibility, of an effect on the body.[158]

[155] United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 480 (E.D. Mich. 1967).
[156] *Id.*
[157] S. Rep. No. 82-946 (1951), at 4, *reprinted in* FDA, *supra* note 32, at 667.
[158] *Decholin*, 264 F. Supp. at 480, 484.

At the very most, the "other potentialities" and "collateral measures" prongs are ambiguous as to whether consideration of social policy is allowed. This ambiguity is insufficient to overcome the conclusion from the Congressional objectives that consideration of social harms in the Rx-OTC decision is inconsistent with the legislative history of the Durham-Humphrey Amendments.

IV.

The recent debate over the proposed switch of the emergency contraceptive Plan B from prescription to over-the-counter status has brought the Durham-Humphrey Amendment and its distinction between Rx and OTC drugs to the forefront.[159] For this reason, the detailed legislative history provided in Parts II and III is particularly timely and provides useful insight into the appropriateness of considering questions of social harm, rather than just scientific and medical evidence, in determining whether to switch Plan B to nonprescription status. After reviewing the controversy sparked by the proposal to switch Plan B from prescription to nonprescription status, this section applies the conclusions drawn from the legislative history of the Durham-Humphrey Amendments to the Plan B debate.

A.

[159] *See, e.g.,* Gina Kolata, *There's a Blurry Line Between Rx and O.T.C.*, N.Y. TIMES, December 21, 2003, 2003 WLNR 5652528. News reports are not always accurate in their description of the Durham-Humphrey Amendments. The New York Times article cited *supra* stated that the Amendments "gave the F.D.A. authority to make th[e] determination" as to whether a drug was prescription or nonprescription. *Id.*

A Brief History of the Debate Over Whether to Switch Plan B from Prescription to Nonprescription Status

1.

The Initial Application and Not Approvable Letter

On April 16, 2003, Women's Capital Corporation submitted a supplemental new drug application requesting that its emergency contraceptive, Plan B, be switched from prescription-only to over-the-counter status.[160] Pursuant to FDA procedures, this application was submitted to the Offices of Drug Evaluation with responsibility for reproductive drugs and over-the-counter drugs for concurrent review.[161] During this review process, the FDA held a joint public meeting of its Nonprescription Drugs Advisory Committee and its Advisory Committee for Reproductive Health Drugs, which voted 23-4 to recommend approval of Plan B for OTC status on December 16, 2003.[162] The FDA missed its February 22, 2004 goal date for deciding on the Plan B application and extended the deadline to May 21, 2004.[163] On April 2, 2004, the Office of Drug Evaluation III recommended that Plan B be approved for OTC sale without any age restriction; the Office of Drug Evaluation V had made the same recommendation in January.[164] After reviewing the recommendations of the Offices of Drug Evaluation, the Director of the Office of New Drugs likewise recommended that Plan B be approved for OTC sale without restriction on April 22, 2004.[165]

Despite the recommendations of its two advisory committees, its professional staff, the Deputy Directors of two Offices of Drug Evaluation, and the Director of the Office of New Drugs, the FDA issued a not-approvable

[160] *GAO Report*, supra note 2, at 5.
[161] *Id.* at 14.
[162] *Id.*
[163] *Id.* at 15.
[164] *Id.* at 15-16.
[165] *Id.* at 19-20.

letter, rejecting Plan B's application for OTC status, on May 6, 2004.[166] Although regulatory action letters are normally signed by the Directors of the Offices of Drug Evaluation, Dr. Stephen Galson, the Acting Director of FDA's Center for Drug Evaluation and Research (CDER), signed the not-approvable letter because the review staff and the relevant directors disagreed with his conclusion.[167] This was the only one of the 94 action letters regarding Rx to OTC switches issued by the FDA between 1994 and 2004 that was signed by the Director of CDER.[168] In his letter to Barr Pharmaceuticals,[169] Dr. Galson expressed concern about inadequate data supporting safe use by young adolescents without professional supervision[170] and rejected generalization of the actual use data to the whole population of Plan B users "because of inadequate sampling of younger age groups."[171] Dr. Galson's specific concern, according to internal FDA documents, was that young adolescents' lack of cognitive development made extrapolation of data from older populations impossible and would cause higher levels of risky sexual behavior, leading to decreased condom use and increased transmission of STDs.[172] The not-approvable letter gave Barr the option of either providing more data regarding the safe use of Plan B by those under 16 or more support for their proposal to sell Plan B via a prescription for those under 16 and OTC for those over 16.[173]

FDA's review staff, the directors of the relevant offices, and the joint advisory committee all disagreed with Dr. Galson's reasoning. The joint advisory committee unanimously concluded that OTC availability of Plan B would not lead to decreased use of other forms of contraceptives and that Plan B was safe for use in the nonprescription setting; it also voted 27 to 1 that the actual use study was generalizable to the whole population.[174] The FDA's professional staff noted that the FDA did not traditionally differentiate between

[166] *Id.* at 20.
[167] *Plan B Q&A*, *supra* note 2, at 3.
[168] *GAO Report*, *supra* note 2, at 30.
[169] Barr Pharmaceuticals acquired the rights to Plan B from the Women's Capital Corporation in October 2003.
[170] Stephen Galson, *FDA Not Approvable Letter to Barr Research, Inc. For NDA 21-045/S-011 (Plan B)*, at 1 (May 6, 2004), http://www.fda.gov/cder/drug/infopage/planB/planB_NAletter.pdf [hereinafter *Not Approvable Letter*].
[171] *Id.*
[172] *GAO Report*, *supra* note 2, at 23, 48.
[173] *Not Approvable Letter*, *supra* note 170, at 2.
[174] *Letter from 48 Members of Congress to FDA Commissioner Regarding Delay in Plan B Decision*, February 26, 2004, at

older and younger adolescents and, even if it did, additional information requested from the sponsor and ongoing studies refuted the concern that increased access to Plan B would lead to increased risky sexual behavior among teens.[175] Similarly, the Director of the Office of New Drugs stated that the FDA had a "long history" of extrapolating findings from older patients to adolescents and the FDA rarely requested age-specific data.[176] Regardless of normal FDA practice, the review staff noted that sufficient adolescents participated in the actual use study to draw conclusions and, since it was open to all women, the actual use study was representative of Plan B's potential market.[177] In addition to the abnormality of Dr. Galson signing the regulatory letter, a General Accounting Office ("GAO") report concluded that three other aspects of the Plan B review process were unusual: 1) high-level FDA management was abnormally involved; 2) significant evidence indicated that the not approvable decision was made in December or January before the staff review was complete; and 3) Dr. Galson's rationale was novel and not in accord with traditional FDA practices.[178]

2.

The Continuing Saga of the Plan B Rx-OTC Switch

Since its initial not-approvable decision, the FDA has repeatedly promised a final decision on the Plan B Rx

http://www.democrats.reform.house.gov/story.asp?ID=305. The first two votes were not limited to consideration of adolescent behavior, but since adolescents were a significant foreseeable population of Plan B users, the votes certainly took into account concerns about their behavior.

[175] *GAO Report*, *supra* note 2, at 24-26. Dr. Galson concluded that these studies were not reliable because they did not replicate the conditions under which young adolescents would be using OTC Plan B—namely without any assistance or education. *Id.* at 25. However, the joint advisory committee had also voted 27 to 1, based on the actual use study, that consumers (which would include adolescents) could use Plan B appropriately by following the label. *Id.* at 26. *See also* Director, Office of New Drugs, *Official Memorandum on His Decision on the Plan B Application* (April 22, 2004), at 2, *reprinted in GAO Report*, *supra* note 2, at 52 [hereinafter *Office of New Drugs Memo*] ("The Agency has not heretofore distinguished the safety and efficacy of Plan B and other forms of hormonal contraception among different ages of women of childbearing potential and I am not aware of any compelling scientific reason for such a distinction in this case.").

[176] *Office of New Drugs Memo, supra* note 175, at 2.

[177] *GAO Report, supra* note 2, at 27. Likewise, the joint advisory committee "voted 27 to 1 that the actual use study data was generalizable to the overall population of OTC users, including adolescents." *Id.* at 28-29.

[178] *Id.* at 19-29.

to OTC switch but has failed to deliver. In a June 2^{nd} meeting with the chairman of the House subcommittee with oversight for the FDA, Dr. Galson implied that the FDA was likely to approve Plan B within six months for women over age 16.[179] On July 21, 2004, Barr Pharmaceuticals resubmitted its supplemental new drug application and proposed that Plan B be switched to OTC status for women 16 years of age and older only while remaining prescription-only for those under 16.[180] Despite Dr. Galson's implication of a quick decision, the FDA missed its January 2005 target deadline for ruling on the revised supplemental NDA, which FDA Acting Commissioner Lester Crawford admitted was unusual.[181] By March 2005, when Dr. Crawford took to Capitol Hill for confirmation hearings on his nomination to become Commissioner, the FDA still had not made a decision on Barr's second submission, much to the chagrin of several Senators. In response to a question as to when the decision would be issued, Dr. Crawford said, "I wouldn't want to say days. I would say weeks."[182] In addition to stating the decision was imminent, Dr. Crawford, like Dr. Galson before him, implied to Congress that approval was likely, saying that the science was done and only the labeling was left, the FDA "had no real dispute" with the label, and, more explicitly, that "[t]his is going to be a very unusual sort of approval."[183] A few weeks later, when a decision still had not been made on Plan B, Senators Hillary Rodham Clinton, Democrat of New York, and Patty Murray, Democrat of Washington, put a hold on Dr. Crawford's nomination to become Commissioner until the FDA made a Plan B decision.[184] The Senators only lifted their hold when Secretary of Health and Human Services Michael O. Leavitt provided a written

[179]Marc Kaufman, *Staff Scientists Reject FDA's Plan B Reasoning,* WASHINGTON POST, June 18, 2004, at A2, http://www.washingtonpost.com/wp-dyn/articles/A50466-2004Jun17.html; Bob Cusack, *FDA Likely to Approve Plan B Pill*, THE HILL, June 9, 2004, http://www.hillnews.com/news/060904/fda.aspx. It is possible that Congressman Greenwood read too much into what Dr. Galson told him. According to Greenwood, "There was no guarantee from Galson, but he said their only concerns were for girls under 16, and I took that to mean they would approve it OTC for everyone else quite soon." Kaufman, *supra.*

[180]Leslie M. Crawford, *Letter from FDA Commissioner to Duramed Research Stating that FDA is Unable to Make a Decision on Supplemental NDA* (August 26, 2005), at 1, http://www.fda.gov/cder/drug/infopage/planB/Plan_B_letter20050826.pdf [hereinafter *No Decision Letter*].

[181]Harris, *supra* note 1. Dr. Crawford's admission occurred at his confirmation hearings to become Commissioner. *Id.*

[182]*Id.*

[183]Marc Kaufman, *FDA Expects to Ease Plan B Availability,* Washington Post, March 18, 2005, at A10, http://www.washingtonpost.com/wp-dyn/articles/A45610-2005Mar17.html; Harris, *supra* note 1.

[184]Sheryl Gay Stolberg, *Democrats Block Nomination Over Morning-After Pill*, N.Y. TIMES, April 7, 2005, at A19, 2005 WLNR 5415573.

promise that the FDA would act on the resubmitted supplemental NDA by September 1, 2005, almost eight months after a decision was originally due.[185]

Despite Dr. Crawford's Senate testimony that a decision, likely positive, was imminent and Secretary Leavitt's written promise that a decision would be made by September 1^{st}, on August 26, 2005, Dr. Crawford sent a letter to Barr Pharmaceuticals saying that, while the FDA had concluded that Plan B was appropriate for OTC status for women age 17 and older, it was "unable at this time to reach a decision on the approvability of the application."[186] The FDA cited concerns as to whether it had authority to allow a drug to be marketed as both Rx and OTC at the same time, whether a drug may be both Rx and OTC based on the age of the individual, whether an age-based distinction could be enforced, and whether Rx and OTC versions of the same product can be marketed in the same package.[187] At the same time, the FDA issued an advance notice of proposed rulemaking requesting comments on whether it should initiate a rulemaking to codify its interpretation that, on rare occasions, Section 503(b) of the FD&C Act allows an active ingredient to be marketed as both a prescription and a nonprescription drug at the same time.[188] Although Senators Clinton and Murray claimed that their agreement had been violated, Secretary Leavitt asserted that the indefinite delay of decision was "an action" within the meaning of his written promise to the Senators.[189]

In May 2006, over three years after Plan B's switch to OTC status was first proposed and over a year after the FDA was supposed to make its decision on Barr's resubmitted application, the FDA's decision was still indefinitely delayed. In response, Senators Clinton and Murray vowed in March to block another nominee for FDA Commissioner until a decision was made.[190] Thus, the strange history of Plan B continues.

[185] Gardiner Harris, *Official Quits on Pill Delay at the F.D.A.*, N.Y. TIMES, September 1, 2005, at A12, 2005 WLNR 13732211.
[186] *No Decision Letter*, *supra* note 180, at 1.
[187] *Id.*
[188] Advance Notice of Proposed Rulemaking, *Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product*, 70 Fed. Reg. 52050 (2005), available at http://www.fda.gov/OHRMS/DOCKETS/98fr/05n-0345-nap001.pdf.
[189] Harris, *supra* note 185.
[190] Editorial, *Time to Stall Bush Nominee,* N.Y. TIMES, March 25, 2006, http://www.nytimes.com/2006/03/25/opinion/25sat1.html.

B.

Social Harms, the Plan B Decision, and the Durham-Humphrey Amendments

As discussed *supra*, the legislative history of the Durham-Humphrey Amendments limits the Rx-OTC decision to scientific and medical considerations. According to both Dr. Galson,[191] who was responsible for the initial not-approvable letter, and Dr. Crawford,[192] who issued the subsequent no decision determination, the FDA's decision was based just on questions of science and did not consider politics or social policy. However, it is far from clear that these official explanations reflect what really happened.

Neither Dr. Galson, nor anyone else involved in the Plan B approval process, has suggested that Plan B itself, even with repeated uses, has a harmful effect on the consumer's body.[193] Instead, Dr. Galson's official reason for issuing the not-approvable letter was the inadequacy of evidence that young adolescents could use Plan B safely without supervision; specifically, he was concerned that their immature cognitive development would lead them to engage in increased risky sexual behavior knowing that Plan B was easily available.[194] To the extent that his concerns regarding promiscuity merely reflected societal disapproval of teen sexual activity, or at least of frequent teen sexual activity with various partners, this would be a concern solely relating to Plan B's effect on behavior, a social consideration inconsistent with the legislative history of the Durham-Humphrey Amendments. In fact, Dr. Galson admitted the inappropriateness of such a consideration, saying, "Some staff have expressed the concern that this decision is based on non-medical implications

[191] Cusack, supra note 179 ("Galson has said that his May 6 decision on Plan B was not influenced by political pressure and that the White House was not involved."); Acting Director, Center for Drug Evaluation and Research, *Official Memorandum Explaining His Not-Approvable Decision* (May 6, 2004), at 2, *reprinted in GAO Report*, *supra* note 2, at 49 [hereinafter *Galson memo*] ("Some staff have expressed the concern that this decision is based on non-medical implications of teen sexual behavior, or judgments about the propriety of this activity. These issues are beyond the scope of our drug approval process, and I have not considered them in this decision.").

[192] Harris, *supra* note 1 ("I can assure you that this decision will not be based on politics. It will be based on science.").

[193] *But see* Gina Kolata, *Debate on Selling Morning-After Pill Over the Counter,* N.Y. Times, December 12, 2003, at A1, 2003 WLNR 5670940 ("Opponents say the over-the-counter rule would be an invitation to medical nightmares, with some people, particularly teenagers, using the pills repeatedly and not telling anyone even if they have complications. The safety of repeated use has not been well studied."). This story was written very early in the Plan B OTC approval process, and no one in the FDA, or even opponents of Plan B outside of the FDA, has suggested recently that Plan B itself poses a safety risk. Instead, the focus has been on Plan B's effect on teen sexual behavior.

[194] *See supra,* Part IVA, Section 1.

of teen sexual behavior, or judgments about the propriety of this activity. These issues are beyond the scope of our drug approval process, and I have not considered them in this decision."[195] Instead, he claimed his real concern was that easy access to Plan B would increase transmission of sexual diseases through the combination of increased promiscuity and decreased condom use.[196] If it could be persuasively demonstrated that increased access to Plan B had a causal relationship to increased promiscuity and decreased condom use which in turn had a causal relationship to increased transmission of STDs, this would be an effect, albeit indirect, of Plan B on the body of the consumer and therefore a scientific or medical harm. Under the legislative history of the Durham-Humphrey Amendments, such consideration would be appropriate under either the "other potentialities for harmful effect" or "collateral measures necessary to its use" prong.

For two reasons, however, Dr. Galson's consideration of promiscuity, condom use, and STDs is inconsistent with the legislative history of the Durham-Humphrey Amendments. First, it fails the requirement, necessitated by the common definition of "unsafe," that there be a reasonable probability, not a mere possibility, that the medical or scientific harm—in this case, the increased transmission of sexual diseases—will actually result.[197] The chain of reasoning requires one to assume: 1) adolescents prior to engaging in sexual activity will know about the easy availability of Plan B; 2) they will be thinking about this easy availability in making decisions regarding sexual activity; 3) because of the easy availability of Plan B, they will have more sex with more partners using less protection; 4) increased transmission of sexual disease will result; and 5) the sexual disease will cause actual harm. Given that this reasoning requires consideration of how people would change their behavior if the drug were more easily accessible, essentially a social question unusual for the Rx-OTC switch,[198] it seems too attenuated to fit within the ordinary definition of "unsafe" envisioned by

[195] *Galson memo, supra* note 191, at 2.
[196] *GAO Report, supra* note 2, at 23.
[197] *See* United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 480 (E.D. Mich. 1967); *see generally, supra*, Part IIIB, Section 3.
[198] Gardiner Harris, *Morning-After-Pill Ruling Defies Norm*, N.Y. Times, May 8, 2004, at A13, 2004 WLNR 5363030. The unprecedented nature of consideration of how behavior might change based on the availability of a drug was raised by a representative of Planned Parenthood and therefore is admittedly of questionable reliability. However, the reasoning was quite

the legislative history. In fact, the Director of one Office of Drug Evaluation called Dr. Galson's concern as to increased STD transmission "speculative."[199]

More importantly, Dr. Galson's medical rationale was inappropriate for the Rx-OTC determination because it was not generally accepted, as Congress intended medical or scientific considerations to be. For starters, the OTC status of Plan B is supported by leading medical associations, including the American Medical Association and, in particular given Dr. Galson's concern about adolescent use, the American Academy of Pediatrics and the Society for Adolescent Medicine.[200] Furthermore, the joint advisory committee, made up of leading scientific experts on both OTC and reproductive issues, rejected Dr. Galson's concerns as "unsupported by existing studies, common sense and real world experience," voting 27 to 1 that the actual use study was generalizable to the whole population of potential users and 23 to 4 to approve Plan B's OTC status.[201] This was the only example in the past ten years where the FDA refused to follow an advisory committee's recommendation to switch a drug to OTC status.[202] Similarly, the FDA's professional staff, after considering all five studies that provided emergency contraceptives in advance to study participants to assess the behavioral impact of OTC access, rejected the assertion that easy access to Plan B could lead to increased risky sexual behavior, concluding that it did not lead to use as a substitute form of birth control, did not increase the number of sexual partners or frequency of unprotected sex, and did not increase the frequency of STDs.[203] Dr. Galson admitted that it was uncommon to overrule staff recommendations, saying

persuasive. He noted that the FDA certainly would not "ask the makers of anticholesterol pills if people would eat more cheeseburgers when their drugs became available over the counter." *Id.*

[199] Kaufman, *supra* note 183.

[200] *See* National Partnership for Women & Families, *Testimony in Support of Over-the-Counter (OTC) Status for Plan B Before the FDA Joint Advisory Committee*, December 16, 2003, at http://www.nationalpartnership.org/portals/p3/library/ReproHealthMedicalTech/PlanBTestimonyDec03.pdf; *Letter from 48 Members of Congress to FDA Commissioner Regarding Delay in Plan B Decision, supra* note 174. Other medical groups endorsing OTC availability for Plan B included the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists, as well as more than seventy other medical and public health organizations. *See* National Partnership for Women & Families, *supra*.

[201] Editorial, *Science or Politics at the F.D.A.?*, N.Y. Times, February 24, 2004, at A24, 2004 WLNR 5575199; *GAO Report*, *supra* note 2, at 28-29.

[202] *GAO Report*, *supra* note 2, at 29.

[203] *Id.* at 25-27. Only one member of the review staff thought there was any reason to be concerned about a possible increase in sexual behavior, asserting that the data was inadequate. However, that staff member still recommended an approvable decision.

that it occurred only one other time in the past 10 years; overruling both an advisory committee and staff recommendation may be even rarer, with several former FDA officials saying they could not think of a single other instance where this occurred.[204] Dr. Galson's only scientific or medical support—beyond his own opinion that the studies were inconclusive because they did not sufficiently replicate the conditions of OTC Plan B use—was a minority report filed by one dissident member of the joint advisory committee.[205] This seems to confirm the concerns expressed during the Durham-Humphrey Amendment debate that the scientific opinion version would insufficiently constrain the Administrator because he "could select the particular experts who hold opinions that suit his purpose."[206] Though increased transmission of sexual diseases is appropriately labeled scientific or medical, the concern is speculative and not supported by generally accepted scientific opinions. Thus, it is an inappropriate consideration for the Rx-OTC switch under the legislative history of Section 503(b).

Despite Dr. Galson's assertion that social harms and politics played no role in his decision, many have concluded to the contrary based on the speculative nature of, and the lack of support for, the STD concern. Even within the FDA, the Director of the Office of New Drugs suggested this interpretation in an internal memorandum, saying,

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Id. at 26 n.46.

[204]Harris, *supra* note 198.

[205]The minority report was written by Dr. David Hager, a Kentucky gynecologist and strong anti-abortion advocate who refuses to prescribe Plan B to his patients. Dr. Hager alleged that someone at the FDA asked him to the write the minority report, which cited the same concerns that would eventually be given in the not approvable letter. Lesley Stahl, *The Debate Over Plan B*, CBS News, Nov. 27, 2005, at http://www.cbsnews.com/stories /2005/11/22/60minutes/main1068924.shtml. Despite Dr. Hager's allegations, the FDA denied that it requested the minority report. *See GAO Report*, *supra* note 2, at 14 n.32

[206]*Senate Hearings*, 82nd Cong. 146 (1951), *reprinted in* FDA, *supra* note 32, at 509 (statement of Dr. Frederick J. Cullen, Executive Vice President of the Proprietary Association of Washington, D.C.).

> Products that are indicated for uses related to sexual activity in adolescents raise concerns for some people that go beyond a finding based on clinical trial data that the product is safe and effective for its intended use in adolescents. These concerns are derived from individual views and attitudes about the morality of adolescent sexual behavior and also overlap with concerns about the role for parents and health care professionals in decisions about contraceptive use in adolescents. . . .While OTC access to Plan B for adolescents may be controversial from a societal perspective, I cannot think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling.[207]

Consistent with this view, some critics assert that the decision was actually based on FDA concerns over social harms, such as the possible increase in promiscuity and the belief that use of Plan B is a form of abortion.[208] Other critics assert that the decision was made in response to pressure from conservatives and the White House,[209] whose traditional stances on moral and reproductive issues made these potential social harms particularly worrisome. In addition to Dr. Galson's nearly unprecedented overruling of the recommendations of both the FDA staff and joint advisory committee, indications of outside pressure in the FDA decision-making process include: that the Commissioner of the FDA recommended a not-approvable letter; that the decision was made at a higher level than the Office of Drug Evaluation, contrary to normal practice; that the decision to deny approval to Plan B allegedly was made in December or January, several months before the review process was complete; that someone within the FDA may have requested a minority opinion from a member of the advisory panel;[210] and that Dr. Susan F. Wood, Director of FDA's Office of Woman's Health, quit because she thought abortion politics were trumping the scientific and medical evidence.[211]

Consultation between the political branches and the FDA during the Rx-OTC approval process is not in itself inappropriate under the legislative history of the Durham-Humphrey Amendments. In fact, it promotes

[208] Rubin, *supra* note 5.
[209] *Id.*
[210] *See GAO Report*, *supra* note 2, at 14 n.32 & 16-22.
[211] Harris, *supra* note 185.

the accountability that many members of Congress were concerned would be lacking if the FDA made the Rx-OTC determination. However, if the FDA acted in response to social harms, either on their own or in response to pressure from political actors, in denying OTC status to Plan B, their decision contravened the legislative history of the Durham-Humphrey Amendments. Even if the decision was actually based on the scientific rationale asserted by the FDA—concern about increased transmission of STDs—the FDA's decision was still inconsistent with Congressional intent because their scientific considerations were only speculative and inadequately accepted by expert medical and scientific opinion.[212]

V.

The best conclusion to be drawn from the prior sections is that the Plan B decision was inconsistent with the legislative history of the Durham-Humphrey Amendments, the governing legislative standard for the Rx-OTC switch determination. Since administrative agencies like the FDA derive their authority from Congress,[213] a decision by the FDA inconsistent with the power delegated by Congress exceeds the scope of its authority and is therefore illegitimate.[214] If this is true of the Plan B decision, it must be equally true of every Rx-OTC decision that considers social harms. And yet, despite the absence of social harms in the

[212] Dr. Crawford's August 2005 decision focused on FDA authority, labeling, and packaging and therefore did not directly implicate the definition of a prescription drug or the legislative history of the Durham-Humphrey Amendments. However, even though the FDA had long interpreted Section 503(b) to allow simultaneous marketing of an active ingredient as both prescription-only and OTC, it decided suddenly with Plan B to engage in rule-making to codify this interpretation, a decision that was sure to engender delays. *See* Advance Notice of Proposed Rulemaking, *supra* note 188, at 4-5. From this, it is possible to conclude that these superficial FDA concerns actually provided cover for considerations of social harm.

[213] *See* Alfred C. Aman, Jr. & William T. Mayton, Administrative Law 1 (2d ed. 2001) ("Agencies are generally created by, and draw their power from, the legislature.").

[214] *See* Whitman v. American Trucking Ass'n, 531 U.S. 457, 472 (2001) (quoting J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928)) (noting that agency decision-making must conform to an intelligible principle provided by Congress in a legislative act).

FDA's official Rx-OTC switch policy,[215] both common sense and reasoned analysis by the commentators[216] suggest that the FDA must consider at least some social harms on at least some Rx-OTC decisions. Does this mean that the FDA is systematically exceeding the scope of its delegated authority? Probably not. Changed circumstances since 1951 have undermined the basis on which the Congressional intent for the Durham-Humphrey Amendments rested and support the consideration of at least some social harms in at least some circumstances. In particular, the 1962 Drug Amendments revealed a different Congressional vision of drug regulation from that in 1951 and suggest that, while Congress did not alter the Rx-OTC standard, the authority it delegated to the FDA under it changed significantly after 1962. Thus, a brief consideration of the 1962 Drug Amendments is necessary to truly understand the appropriate role of social harms in the Plan B Rx-OTC decision.[217]

A. Changed Circumstances and a Changed Congressional Intent?

Subsequent events since 1951 have undermined all four Congressional objectives that supported limiting the Rx-OTC decision to medical or scientific considerations. The strong emphasis on self-medication reflected in the Durham-Humphrey debates[218] dimmed after 1951 as the "therapeutic revolution" that began in the 1930s and accelerated after World War II brought an explosion of new drugs. [219] Reasonable concerns about the greater potency of these new drugs caused manufacturers, with the FDA's assent, to limit them to

[215] *See* Rheinstein, *supra* note 19, at 140-142; *see also Galson memo*, *supra* note 191, at 49 (stating that the non-medical implications of teen sexual behavior or judgments about its propriety "are beyond the scope of our drug approval process.")

[216] *See* Pray, *supra* note 8, at 186 (noting that the agency often considers other factors, such as social impact, in the Rx-OTC decision even though it is not in the formal policy); Hutt, *supra* note 10, at 438 ("It is readily apparent, however, that many determinations of prescription/nonprescription status depend in large measure upon unarticulated principles of social policy.").

[217] Since the focus of this paper is on the Durham-Humphrey Amendments and their relationship to the Plan B decision, detailed consideration of the 1962 Drug Amendments is beyond its scope. However, an admittedly not comprehensive inquiry into the changes made by the Amendments is necessary to truly understand the relationship between social harms, the Plan B decision, and the Durham-Humphrey Amendments.

[218] *See* Part IIIA, Section 3.

[219] *See generally* Temin, *supra* note 8, at 58-82.

prescription-only, resulting in a system that emphasized the "doctor's power to heal the patient, as opposed to assisting sick people to heal themselves."[220] The requisite knowledge consumers would need to make choices between the increased number of potent and complex drugs means that the traditional notion of self-medication is no longer a viable option.[221]

In response to the therapeutic revolution, the 1962 Drug Amendments fundamentally altered the power given by Congress to the FDA. Two changes are particularly relevant for present purposes. First, the 1962 Act required the FDA to find substantial evidence of effectiveness in order to approve a new drug or keep an approved drug on the market.[222] Since the Drug Amendments applied to OTC drugs introduced to the market after 1938,[223] Congress in 1962 expressly departed from one of its objectives in enacting the Durham-Humphrey Amendments: to eliminate the effectiveness requirement for OTC marketing. Congress' elimination in 1951, and subsequent reinclusion in 1962, of efficacy is of admittedly limited relevance to the consideration social harms, but it does reveal a broadening of the Rx-OTC determination after 1962 and casts some doubt on the continuing importance of the legislative history of the Durham-Humphrey Amendments.

[220] *Id.* at 82-83. The declining emphasis on self-medication is revealed by pharmaceutical manufacturers' distribution of advertising dollars: the share of advertising dollars directed at consumers (rather than doctors) went from 90% around 1930 to 20% in 1972. *Id.* at 84. Whether this was the cause (i.e. because manufacturers were directing less advertising at them, consumers were unable to choose between drugs and thereby needed the help of a doctor) or the effect (i.e. because consumers were relying on doctors rather than self-medicating, there was no need to direct advertising at them), it shows a substantial erosion in self-medication in the United States in the period just before and after the passage of the Durham-Humphrey Amendments.

[221] *Id.* at 119. However, several commentators have noted a recent increase in emphasis on self-medication as a way to reduce healthcare costs by avoiding visits to the doctor. *See* Stephen Paul Mahinka & M. Elizabeth Bierman, *Direct to OTC Marketing of Drugs: Possible Approaches,* 50 Food & Drug L.J. 49, 50 (1995) ("[P]harmaceutical companies are facing increasing political and economic pressures to reduce health care costs by encouraging appropriate self-medication efforts."); Henri R. Manasse, Jr. & Hong Xiao, *Scope of Medication Use in the United States and Attendant Issues,* 44 Drake L. Rev. 471, 471-472 (1996) ("Self-medication and OTC drugs have become increasingly popular as the self-care movement has expanded and as individuals act to reduce their personal expenditures for physician visits."). Insurance companies and managed care organizations, not consumers, are likely to benefit from this new emphasis, as insurance reimbursement and tax deductions often make prescription drugs cheaper to consumers than their OTC counterparts. *See* Lance W. Rook, *Listening to Zantac: The Role of Nonprescription Drugs in Health Care Reform and the Federal Tax System*, 62 Tenn. L. Rev. 107, 108-109 (1994); *see also* Pray, *supra* note 8, at 179 (noting that a managed care company in 2001 petitioned the FDA to switch three allergy medicines from Rx to OTC status).

[222] *See* Notes, *Drug Efficacy and the 1962 Drug Amendments*, 60 Geo. L.J. 185, 192-193 (1971).

[223] *See* Peter Barton Hutt & Richard A. Merrill, Food and Drug Law: Cases and Materials 478, 588 (2d ed. 1991).

The 1962 Drug Amendments also changed the nature of the FDA's new drug regulation from pre-market review to pre-market approval. Prior to 1962, a drug was approved for marketing unless the FDA objected within 60 days of submission of an NDA that the drug was unsafe.[224] This delegated to the drug manufacturer the primary obligation for applying the definition of a prescription drug, with the FDA limited to proving that the drug was not safe for nonprescription sale if it disagreed with the manufacturer's determination. By contrast, the 1962 Drug Amendments required affirmative FDA approval[225] for all OTC drugs introduced since 1938.[226] This required the FDA to itself apply the definition of prescription drugs in the first instance to determine whether a drug should be prescription-only or OTC. Thus, Congress in 1962 enacted, in function if not form, the administrative definition of a prescription drug resisted so vehemently (and successfully) by the pharmaceutical industry and their Congressional supporters in 1951. This expanded FDA role also provided new life to the provision of the Durham-Humphrey Amendments making drugs prescription-only if they were so limited by their NDAs.[227] Prior to 1962, this provision was inconsistent with the Congressional intent to severely limit the power of the FDA in the Rx-OTC decision and is best explained by a failure of Congress to appreciate its significance.[228] But given the FDA's post-1962 ability to reject marketing approval of a drug, allowing the FDA to limit a drug to prescription-only status as a condition for approval of an NDA is well within the authority Congress delegated to the FDA. Thus, with the new power of pre-market approval and the existing, though perhaps dormant, power to make the Rx-OTC decision in the NDA, the FDA after 1962 had essentially the same authority to create an administrative listing of prescription-only drugs rejected by Congress in 1951. The FDA's expanded role minimizes

[224] *See* Notes, *supra* note 222, at 188-189. Thus, the FDA did play a role in defining a prescription-only drug. If it disagreed with the manufacturer's choice, it could object to the proposed OTC labeling as unsafe. However, it would have the burden to prove this. Absent such affirmative action by the FDA, the manufacturer would be responsible for the ultimate determination as to whether the drug was Rx or OTC.

[225] *See id.* at 192.

[226] *See* Hutt & Merrill, *supra* note 223, at 478, 588.

[227] *See* 21 U.S.C. §353(b)(1)(B) (2006) (requiring a drug to be dispensed only by prescription if it "is limited by an approved application under section 355 of this title [the new drug section] to use under the professional supervision of a practitioner licensed by law to administer such drug").

[228] *See supra*, n. 90 & Part IIIA, Section 1.

any inconsistency that would result from consideration of social harms by varying manufacturers since the FDA can insure that similar products are marketed in the same manner.[229]

Moreover, the 1962 Drug Amendments gave to the FDA the primary role in making the Rx-OTC determination, the very power that Congress sought to prevent in enacting its chosen definition in the Durham-Humphrey Amendments. Thus, Congress effectively reversed its 1951 objective of limiting the power of the FDA and instead determined that broad FDA discretion was necessary for effective regulation of the drug industry. Given this broad discretion and the revitalized NDA provision of the Durham-Humphrey Amendments, consideration of social harms is far more appropriate now than it was under the FDA's limited powers in 1951.

More fundamentally, Congress expanded the powers delegated to the FDA in making the Rx-OTC decision in 1962, though leaving the statutory standard unchanged. Prior to 1962, Congress had essentially determined that for all non-dangerous drugs, the benefits of easy access outweighed any other considerations, including social harms. The FDA was merely delegated the authority to weed out dangerous drugs (i.e. those with significant medical or scientific harms) through its power to object to unsafe drugs. For the FDA to consider social harms in a regime where new drugs could be marketed unless the FDA could prove they were unsafe would undermine social policy choices already implicitly made by Congress and exceed the scope of its delegation. However, the affirmative FDA approval of drugs, including OTC drugs introduced since 1938, required by the 1962 Drug Amendments effectively withdrew Congress' wholesale determination that all drugs should be available for self-medication as long as they were not dangerous. Instead, Congress delegated to the FDA the role of weighing the benefits and costs of drugs on an individual basis to determine whether marketing of the drug, or OTC marketing in particular, was in the best interest of society.[230] Since

[229]The power of the FDA to insure consistency is demonstrated by its ability to switch a drug from prescription to OTC without the consent of the manufacturer via the switch regulation. *See* PRAY, *supra* note 8, at 178.

[230]*See* TEMIN, *supra* note 8, at 127-128, 138 (describing the 1962 Drug Amendments move to having the FDA, rather than consumers or doctors, judge the worthiness of a drug); *see also id.* at 202 (detailing the hierarchical structure of the drug market today where the FDA and its expert panels have complete control over the drugs that can be prescribed and sometimes

certain social harms are real societal costs of marketing an OTC drug—for example, if prescription-only status would be unprofitable for manufacturers and deter drug development—failure to consider these would skew the FDA's determination, leading to a sub-optimal level of OTC switches. Thus, while considering social harms would have exceeded Congress' pre-1962 delegation of authority to the FDA, failing to consider any social harms after 1962 would prevent the FDA from doing the full job delegated to it by Congress.[231]

B.

Did the FDA's Plan B Decision Exceed the Scope of Its Delegated Powers?

The increased authority delegated to the FDA in the 1962 Drug Amendments suggests that at least some social harms are appropriately considered in the Rx-OTC decision. However, given the contrary conclusions from the legislative history of the Durham-Humphrey Amendments, social harms should only be considered if they relate to the additional power delegated by Congress to the FDA in 1962.[232] Thus, they should reflect true costs that must be weighed in determining whether OTC marketing of a drug is in the best interest of society. No perfect line can be drawn between acceptable and unacceptable consideration of social harms,[233]

even when they can be prescribed). Although this is an accurate description of the role of the FDA in the post-1962 world, it should be noted that not all commentators support this role; some argue that people, in consultation with their doctors, should be able to take risks that the FDA does not consider acceptable in order to treat, for example, terminal conditions. *See id.* at 204-215; *see also* Peter Barton Hutt, *Laetrile Decision Ignores Constitutional Question,* Legal Times of Washington, July 2, 1979, *reprinted in* Hutt & Merrill, *supra* note 223, at 585.

[231] Since the textual definition of a prescription drug is unaltered from that enacted in 1951, a textual hook for consideration of social harms is necessary. Although Part IIIB, *supra*, concluded that Congress did not intend the "other potentialities for harmful effect" or "collateral measures necessary to its use" prongs to allow social harms, these provisions should be given the broad reading allowed by their text in light of the changed Congressional intent represented by the 1962 Drug Amendments. For similar reasons, the ordinary definition of safety should be read as covering at least some social harms.

[232] *See* Aman & Mayton, *supra* note 213, at 613 (stating that power delegated by Congressional statutes to agencies "defines the scope of the agency's authority").

[233] For example, assertions by the FDA or Plan B opponents that OTC status would interfere with the obligation of parents of teenagers to participate in and advise their children on major life decisions intuitively seems to be a valid social harm to consider. However, while it would likely pass the generally accepted and reasonably probable requirements discussed *infra*, it would not satisfy the quantifiable requirement, making it an invalid social harm under the proposed standard. Thus, the line drawn between acceptable and unacceptable social harms is not perfect, but it does provide a framework for limiting FDA departure from the legislative history of the Durham-Humphrey Amendments to only that which is necessary to fulfill the FDA's obligations under the 1962 Drug Amendments.

but some general criteria can be identified, criteria that suggest that the FDA exceeded the scope of its authority in making the Plan B decision.

First, only social harms that can be quantified can be weighed in the cost-benefit analysis required by the 1962 Drug Amendments. To the extent that opposition to abortion or conservative religious or social views motivated the FDA, its Plan B decision would fail the quantifiable requirement. On the other hand, if FDA was actually motivated by the social harms it identified—increased promiscuity and decreased condom use—the Plan B decision would satisfy this test. Second, and perhaps most controversially, a social issue can only be considered a true cost to society that must be balanced in the Rx-OTC decision if society generally recognizes it as harmful. For example, Plan B concerns related to abortion would not qualify as an appropriate social consideration because of the American public's deep division over whether abortion is really a societal harm. On the other hand, the FDA's concern about decreased condom use would likely be accepted by the general American public, if not all Americans, as a cost to society. Promiscuity is a much more difficult issue since it could reasonably be argued that the American public is divided on the appropriateness of teen sexual activity. However, it seems correct that most Americans are opposed to teen *promiscuity*—casual sexual relations with a variety of partners. At the very least, the FDA's conclusion that teen promiscuity is a generally recognized social harm would satisfy the limited review standard of the Administrative Procedure Act.[234]

Finally, a potential social harm can only be labeled a cost to society that must be weighed by the FDA if

[234] *See* 5 U.S.C. § 706 (1996). The general review standard in the APA focuses on whether the agency action was arbitrary, capricious, or an abuse of discretion. *Id.* The conclusion that teen promiscuity (as opposed to teen sexual activity) is a generally accepted harm certainly would not be either arbitrary or capricious nor an abuse of the FDA's discretion.

there is a realistic probability, not just the mere possibility, that it will result if the drug is available OTC.[235] If evidence showed that increased promiscuity or decreased condom use were realistic probabilities, these would be acceptable social harms to consider. However, the division within the FDA over whether increased access to Plan B actually affected teen sexual behavior[236] raises the question of whether the claimed social harms were really probable or whether senior FDA officials were inappropriately adding hypothetical social harms to the cost-benefit scale. The FDA review staff pointed to the only five studies to investigate the behavioral impact of easy access to emergency contraceptives and concluded that the evidence showed that Plan B would not be used by adolescents as a substitute for normal contraception, there would not be an increase in the number of sexual partners or the frequency of unprotected sex, and there would not be an increase in the frequency of STDs.[237] In rejecting these conclusions, senior FDA officials expressed doubt as to the reliability of these studies but pointed to no evidence, beyond their own beliefs, to support their conclusion that increased access to Plan B would lead to increased promiscuity and decreased condom use. Thus, unless the FDA can provide evidence to support its conclusions regarding promiscuity and condom use, these social harms seem to be only hypothetical possibilities, not realistic probabilities, and therefore inappropriate for consideration in the Rx-OTC switch.[238]

Given the lack of evidence of scientific or medical harms caused by Plan B, the best conclusion possible is that the FDA rejected Plan B's application for OTC status because of the alleged social harms of increased

[235] *See* United States v. An Article of Drug... "Decholin," 264 F. Supp. 473, 480 (E.D. Mich. 1967).

[236] The FDA review staff, based on the results of all five studies that gave emergency contraceptives to participants in advance to study their behavioral impact, concluded that easier access to emergency contraceptives did not lead to: 1) inappropriate use by adolescents as a substitute form of contraception; 2) an increase in the number of sexual partners or the frequency of unprotected sex; or 3) an increase in the frequency of STDs. *See GAO Report, supra* note 2, at 26-27. Dr. Galson believed that these studies were not reliable since their conditions did not replicate the actual conditions of OTC use. *Id.* at 24-25.

[237] *See GAO Report, supra* note 2, at 26-27.

[238] The lack of any evidence to support the conclusions of senior FDA officials and the contrary evidence relied on by the FDA review staff suggests that a conclusion by the FDA that there is a realistic probability of these social harms would not survive even arbitrary and capricious court review.

teen promiscuity and decreased teen condom use,[239] considerations that are inappropriate under the legislative history of the Durham-Humphrey Amendments. Although the 1962 Drug Amendments expanded the Congressional delegation of Rx-OTC power to the FDA, allowing consideration of quantifiable, generally accepted, reasonably probable social harms, increased teen promiscuity and decreased teen condom use were not reasonably probable. Thus, the FDA's Plan B decision exceeded the scope of its delegated authority.

More concerning than the fact that the FDA exceeded its authority is its repeated denial that social harms factored into its decision. For the administrative state to be consistent with our representative democracy, transparency in decision-making is necessary to insure that agencies remain within the scope of the powers delegated by Congress.[240] In the Plan B context, transparency would have allowed interested parties to demonstrate that the FDA's feared social harms were in fact just mere possibilities, not realistic probabilities. More importantly, transparency would better enable Congress to hold FDA officials accountable for considering inappropriate social harms through Congressional oversight, budget controls, and confirmation hearings. Finally, to the extent that the FDA's considerations reflected the desires of the Bush Administration, transparency would promote accountability at the ballot box.[241] Thus, forthright acknowledgment by the FDA that social harms are influencing an Rx-OTC decision is necessary to insure that the FDA remains within the limited power to consider social harms that results from the interplay of the Durham-Humphrey Amendments and the 1962 Drug Amendments.

[239] *See supra,* Part IVB, Section 1.

[240] *See, e.g.,* Thomas O. McGarity, *Politics By Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103, 203 (2001) ("Transparency is a general desiderata for all regulatory decisionmaking because it helps ensure agency fidelity to statutory policies and thereby increases the confidence of affected citizens in the integrity of the decisionmaking process.")

[241] Political pressure is not generally an appropriate influence on the Rx-OTC determination. However, political pressure that keeps the FDA within Congress' delegation of powers is essential to insuring accountability. For example, political pressure on the FDA to limit its consideration to social harms that are generally accepted or realistically probable provides accountability. By contrast, political pressure on the FDA to consider inappropriate social harms, as may have happened with Plan B, threatens the independence and expertise of the administrative agency.