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The impact of over-the-counter availability of “Plan B” on teens’ contraceptive decision making[☆]

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ABSTRACT

In ruling on the over-the-counter status (OTC) of the emergency contraceptive, “Plan B”, the US Food and Drug Administration (FDA) questioned whether younger adolescent females could adequately self-select and self-medicate. That determination requires a judgment of fact, regarding how increased emergency contraceptive availability would affect adolescents’ behavior, and a judgment of values, regarding the acceptability of different outcomes. We present a general approach to such problems, using analytical and empirical methods grounded in behavioral decision research. We illustrate it with findings from 30 in-depth interviews and follow-up surveys, with adolescent females aged 13–19 in the Pittsburgh area reporting how Plan B availability would affect three decisions (having sex, choosing contraceptives, using Plan B). Although the FDA expressed concern about younger teens using Plan B as their primary form of contraception, neither younger nor older teens revealed such an intention. However, teens preferred easier availability, should emergency contraceptive be needed. Incorporating an understanding of teens’ decision-related perspectives can make such policies more predictable and transparent.

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Plan B is an emergency contraceptive pill that reduces the probability of pregnancy, if two doses are taken within 72–120 h of unprotected sex (von Hertzen et al., 2002). It is available over-the-counter (OTC) in most European countries. In August 2006, the US Food and Drug Administration (FDA) approved OTC sale to women aged 18 and over, in outlets that have accredited pharmacies and avoid selling it to younger women.

In 2003, the drug’s manufacturer, Barr Pharmaceuticals, petitioned FDA to approve OTC status for all women, in additional outlets. Legally, such a petition requires

demonstrating safety and efficacy without physician supervision (Pub. L. No. 82-215, 65 Stat. 648, 1951). The producer submitted clinical trial data, along with behavioral evidence regarding product label comprehension and use, under simulated OTC conditions. It also presented preliminary evidence on the behavior of adolescents given advance access to Plan B (Gold, Wolford, Smith, & Parker, 2004). An advisory panel (Sherman, 2004) recommended OTC status, 23 to 4 (FDA, 2003). However, FDA’s Center for Drug Evaluation and Research (CDER), which governs prescription-to-OTC switches, denied approval (FDA, 2004). CDER’s acting director justified the ruling by denying the relevance of data from older adolescents for younger ones, who might exhibit “impulsive behavior, without the cognitive ability to understand the etiology of their behavior.” This objection departs from earlier agency decisions, holding it “scientifically appropriate to extrapolate data from older to younger adolescents.” (GAO, 2005, p. 5). CDER’s director also expressed concern about “the potential impacts that the OTC marketing of Plan B would have on the

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propensity for younger adolescents to engage in unsafe sexual behaviors due to their possible lack of cognitive maturing compared to older adolescents (GAO, 2005, p. 48)."

At FDA's suggestion, Barr reapplied for OTC approval for women 16 years and older. Despite Congressional threats, FDA missed several deadlines before finally issuing conditional approval. FDA's decision-making process has evoked intense discussion about its interpretation of the behavioral evidence and the role of political pressures (Alonso-Zaldivar, 2005; Dickerson, 2004).

The parties to these debates expressed conflicting theories of teen decision making. Advocates of increased availability argued that OTC status would not undermine teens' current contraceptive practices and might even increase their awareness of contraception options. These advocates also predicted fewer abortions (a health outcome not cited in the law), by reducing unintended pregnancies. Critics predicted that greater emergency contraceptive availability would encourage unprotected intercourse – with Plan B becoming Plan A. If so, then STIs would increase, even if unplanned pregnancies did not. Some critics worried about increased intercourse among unmarried teens, an outcome with no status under the law (FDA, 2003).

A behavioral decision research approach to policy making

The Plan B case represents a common challenge in regulatory rulemaking. An agency must, first, predict the outcomes of proposed policies and, then, determine their acceptability, given its legal mandate. With Plan B, that means estimating the effects of OTC availability on two recognized public health outcomes: unintended pregnancies and sexually transmitted infections (STIs). Barr provided behavioral evidence from simulated OTC conditions. Here, we provide complementary evidence, based on potential users' descriptions of decisions that Plan B availability might affect, without stressing that question or presenting product information.

Behavioral decision research (BDR) offers a systematic way to organize and, if needed, generate the evidence necessary to evaluate alternative policies (Eggers & Fischhoff, 2004). Its application entails two interrelated procedures: *normative analysis*, which formally characterizes the decisions that a policy might affect, and *descriptive research*, which assesses how individuals view those decisions, in terms that allow predicting how optimal their choices will be. Where appropriate, *prescriptive* interventions (e.g., patient package inserts) can attempt to bridge critical gaps between the normative ideal and the descriptive reality (Fischhoff, 1992, 2005; Hastie & Dawes, 2001; vonWinterfeldt & Edwards, 1986). Breyer (1993), Camerer, Issacharoff, Loewenstein, O'Donoghue, & Rabin (2003), and Sunstein and Thaler (2003) offer other BDR approaches to regulating consumer decisions, drawing on general behavioral principles, rather than decision-specific assessments.

The next section presents normative analyses of three decisions that Plan B availability might affect. It is followed by sections presenting in-depth interviews about these

decisions and a structured survey focused on critical beliefs revealed by the contrast between the interviews and normative analyses. Both descriptive studies over-sample low-income, urban female adolescents, a population at high risk for unprotected intercourse, unintended pregnancies, and STIs (Alan Guttmacher Institute, 2004; CDC, 1996; Finer & Henshaw, 2006), two health outcomes cited by FDA in its Plan B decisions. To the best of our knowledge, no study has considered these decision-making processes as fully.

Normative decision analysis

We first examine the two focal decisions mentioned explicitly by FDA, from the perspective of women making them. The first decision is that facing women who suspect that their birth control has failed. FDA's advisory panel focused on how Plan B's availability, safety, and efficacy would affect this decision. The second decision is women's choice of contraceptive methods, cited by FDA in overruling its advisory panel.

Fig. 1 presents a simple decision tree for whether to use Plan B after suspected contraceptive failure. The square *decision node* represents that choice. A woman who chooses not to use Plan B (the lower branch) faces some probability of becoming pregnant, represented by the circular *chance node*, leading to the two possible outcomes. A woman who chooses to use Plan B (the upper branch) may implement this decision at different times, represented here as follows: (a) within 24 h (when it is maximally effective), (b) within 120 h (when still somewhat effective), and (c) not at all, because she cannot access it. If she uses Plan B, then there is some chance of adverse events, which should be similar whenever she takes it. Her probability of pregnancy depends only on Plan B timing – which partly depends on FDA's ruling. Women who cannot access Plan B have the same probability of pregnancy as women who choose not to use it. The analysis omits other possible outcomes not in FDA's charge or seemingly unaffected by its ruling (e.g., abortion, miscarriage, and carrying the pregnancy to term).

Predicting these outcomes requires estimating the decision tree parameters. The research literature provides estimates for the probability of pregnancy. For Plan B users, it increases with time until use (from 0.5% within 24 h to 4.1% at 72 h), approaching the probability for non-users at 120 h (Piaggio, von Hertzen, Grimes, Van Look, 1999). Plan B is thought to prevent an egg from being fertilized or from being implanted in the uterus, once fertilized, but not to affect implanted eggs (Croxatto et al., 2001; Davidoff & Trussell, 2006). Adverse events include abdominal cramping, nausea, vomiting, and headache. The advisory panel received clinical trial evidence on their frequency, before concluding 28 to 0 that Plan B is safe for OTC use (FDA, 2003, p. 364). Thus, the panel's implicit decision tree included these risks, which were deemed less than the benefits of making Plan B available OTC.

FDA did not reject the panel's conclusions regarding Plan B's safety and effectiveness, thereby accepting its normative analysis of the choice in Fig. 1. FDA's initial denial and subsequent indecision focused, instead, on how OTC availability would affect younger women's decisions about

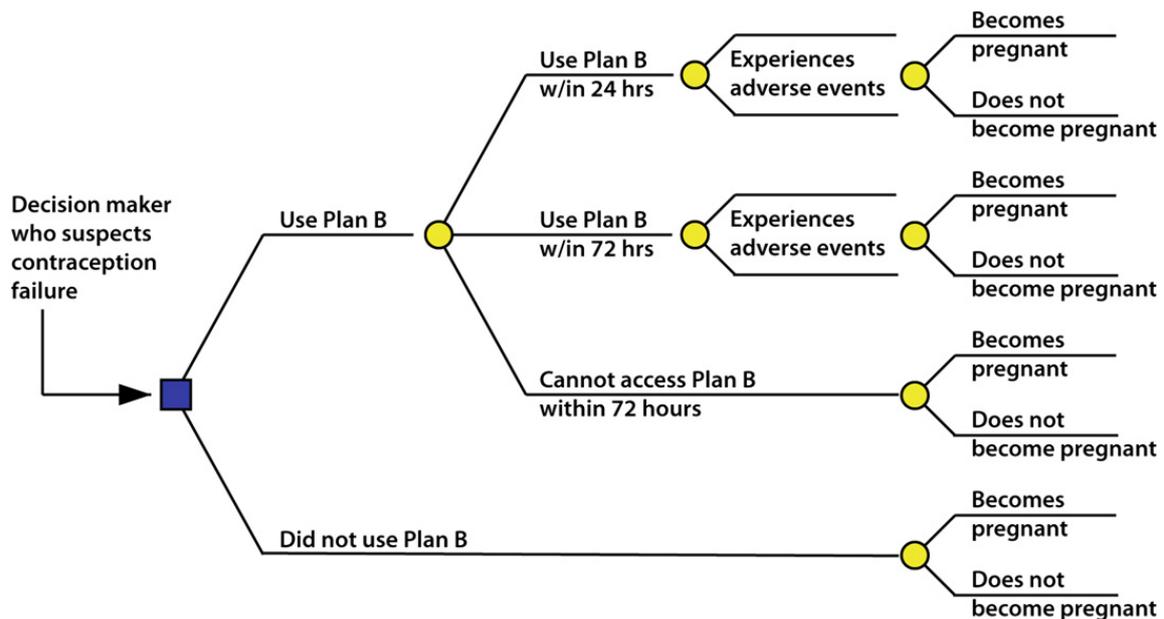


Fig. 1. Decision tree for emergency contraception use, conditional on suspecting failure of primary contraceptive method.

their primary contraceptive method. The analogous decision tree (not shown) has a branch for each method, with its outcomes, including the risks of STIs and method failure leading to pregnancy, whose probability depends on whether women suspect failure. Women who do, then face the decision in Fig. 1. Those who do not, then face a higher probability of pregnancy, given their zero probability of taking Plan B.

How women make these choices depends on how they view their options. Some of these perceptions might be intuited. For example, Plan B's OTC availability should not affect judgments of STI risks. It might, however, affect judgments related to condoms, if greater Plan B availability encouraged women to press their partners to report condom failures – information that they can now use. Greater availability might, similarly, encourage more realistic beliefs about condom effectiveness. Greater control over pregnancy risk might free attention for reducing STI risks.

The best evidence for evaluating such speculations comes from field trials. In a study with adult women, Raymond, Trussell, and Polis (2007) found similar sexual behavior, including condom use, among women given Plan B to use at their discretion and women with pharmacy access. FDA chose to ignore such studies, arguing that adolescents might behave differently. The studies presented here examine one possible reason for such concern: teens lack critical facts about these decisions.

A second possible reason is that teens lack the decision-making skills needed to use whatever facts they have. Research into adolescent decision making suggests that the latter possibility should not be an overwhelming concern. By the mid-teen years, adolescents possess most of the cognitive skills of adults (Fischhoff et al., 2000; Flavell, 1992; Furby & Beyth-Marom, 1992; Jacobs & Kaczynski, 2005; Mann, Harmoni & Power, 1989). However, possessing these skills does not guarantee using them (for adults or adolescents). Actual behavior also reflects social and

emotional processes, which can affect cognitive processes and be affected by them (e.g., feelings of efficacy or frustration shaped by how well situations are understood) (Cauffman & Steinberg, 2000; Downs et al., 2004; Fischhoff, 2008; Reyna & Farley, 2006). A recent issue of *Developmental Review* provides multiple perspectives on the relationship between cognitive skills and performance, under the time, social, and emotional realities of actual choices (Casey, Getz, & Galvan, 2008; Fischhoff, 2008; Gerrard, Gibbons, Houlihan, Stock, & Pomery, 2008; Rivers, Reyna, & Mills, 2008; Steinberg, 2008).

Our goal is to describe adolescents' beliefs and values relative to the issues arising in the normative analysis of decisions potentially affected by Plan B availability. That picture might be seen as a performance ceiling, representing how thoughtfully those decisions might be made – assuming that, the clearer teens' views are, the more likely they to act on them. We use the *mental models* approach to elicit these views. It begins with semi-structured, open-ended interviews, hoping to capture teens' views in their intuitive formulation, followed by structured surveys, hoping to estimate their prevalence – using the issues and formulations emerging from the interviews. Both focus on the topics identified by normative analyses of decisions (like Fig. 1) and of the processes determining the decisions' outcomes, represented in *influence diagrams*, like that presented in Fig. 2. Understanding those shaping processes can afford credibility to estimates of risks and benefits and a feeling of self-efficacy to those making these decisions (Downs et al., 2004; Morgan, Fischhoff, Bostrom, & Atman, 2001).

Modeling influences on adolescent sexual decision making

Fig. 2 provides a qualitative summary of scientific knowledge about factors affecting the outcomes of Plan B

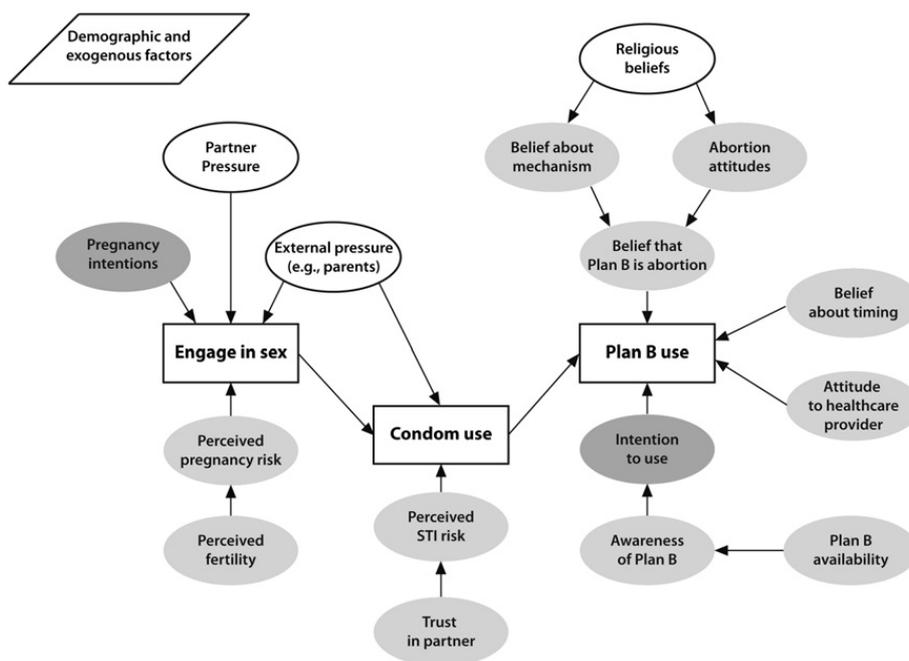


Fig. 2. Influence diagram of factors affecting three sexual decisions.

use (Fig. 1) and the analogous trees (not shown) for decisions about contraceptive use and having sex. It was created through an iterative process, involving literature review and critique by three experts in adolescent sexual behavior. Using the formalisms of influence diagrams (Clemen & Reilly, 2003; Fischhoff, Bruine de Bruin, Guvenc, Caruso, & Brilliant, 2006), it represents choices with rectangular nodes and uncertain factors affecting them with oval nodes. The rhomboidal node captures factors with multiple effects (e.g., age and nature of relationship). In principle, every decision tree has an associated influence diagram, showing the factors predicting its elements. However, these three decisions (Plan B use, contraceptive choice, having sex) are so interrelated that we use a common influence diagram. It adds a concern not mentioned explicitly in FDA's decision, but widely believed to have influenced it: whether Plan B constitutes abortion.

Young women are considered adequately informed if they understand these facts well enough to make personally appropriate choices. The next section reports semi-structured interviews, designed to determine which of these issues are on teens' minds and how they are intuitively formulated. The following section builds on those results with a structured survey estimating the prevalence of specific, decision-relevant beliefs. The ensuing discussion considers how well such verbal reports capture decision-making processes and their policy implications.

Descriptive research: semi-structured interviews

Following Morgan et al. (2001), we created an open-ended interview protocol structured around the topics in Fig. 2. After pretests to improve its flow and clarity, we administered it to 30 young women, drawn primarily from high-risk populations. The protocol was phrased in

terms of teens' beliefs about their friends' behavior, rather than about their own, so as to reduce intrusiveness. If teens recounted personal experiences, those were accepted. Other researchers have studied the accuracy of such beliefs (e.g., Perkins, Meilman, Leichter, Cashin, & Presley, 1999) and teens' tendency to project their own perspectives onto their peers (e.g., Prinstein, Meade, & Cohen, 2003).

Method

Participants

Thirty adolescent females were recruited with fliers posted in their communities in the Pittsburgh area, including organizations serving at-risk youth. Each received \$15 as compensation. Their ages ranged from 13 to 19, with 40% under 16. Two-thirds were African-Americans, 13% Caucasian, 13% bi-racial or mixed race, and 7% Asian.

Procedure

One author (TK) conducted all interviews, in a private room at the Carnegie Mellon University or a community center. Interviews began with open-ended questions about how participants believed their peers made decisions regarding sex and contraception (e.g., "What can be reasons for a girl to have sex?"), with subsequent questions following the natural conversational flow for each topic that participants raised (e.g., Why do you say that? Could you tell me more, so that I can be sure that I understand?). This strategy focuses each interview on topics about which its teen has the most to say. Direct questions asked about the percentage of sexually active individuals among friends and people at the teen's school, the reasons why teens do (and do not) have sex, and the role of partner trust in sexual decisions. Teens who brought up Plan B were asked questions about timing, mechanism, information sources,

experiences, acquisition, and use. Teens who did not mention Plan B received a short description, followed by these questions. Direct questions asked about peers' contraceptive behavior, attitudes toward pregnancy, and reasons for becoming pregnant (or not). Teens were asked about alternatives to giving birth and keeping the child, if pregnant.

Each decision factor that a teen mentioned was written down. During the interview, teens assigned an importance weight to each factor, "I'm going to read back to you the things you've mentioned as being important when someone's deciding to [e.g., have sex]. I'd like you to tell me how important each one is to girls when they are deciding [whether to have sex with someone]. Use a scale from 0 to 100, where 0 would be not important at all and 100 would be most important."

Interviews were taped and transcribed.

Results

Each decision factor in the transcript was coded into Fig. 2, adding any new links that teens raised, without considering their accuracy. Importance weights were added, with the sign indicating whether the teen believed that increasing that variable increased (+) or decreased (–) the variable connected to it – or whether that depends on the circumstances (\pm). The numbers inside each node represent the estimated likelihood of that event.

Fig. 3a and b displays two of the resulting individual mental models. Fig. 3a belongs to a 14-year old who was not sexually active and had had minimal exposure to sex education. Fig. 3b belongs to a sexually active 18-year old, who had completed at least the STI and HIV/AIDS education required in all Pennsylvania public high schools. Gray nodes were mentioned by many teens, but not this individual.

Thus, for example, the teen depicted in Fig. 3a believed that many of her peers were sexually active, increasing their likelihood of deciding to have sex (+80). She saw pregnancy risk as high (95% probability of becoming pregnant through one act of unprotected intercourse) and as strongly influencing (80) the decision to have sex, with the sign (\pm) depending on whether girls want to be pregnant (+) or not (–). Although all questions referred to peers, this teen offered that fear of her parents finding out very strongly influenced her decision not to have sex (–95). Fig. 3a shows her belief that Plan B must be used within 48 h of unprotected intercourse (represented as *timing*). Given this belief, OTC availability should affect decisions about using Plan B, as should whether discussing it with a pharmacist is necessary. Nothing that this teen said suggested any link between decision making about Plan B use, or the factors affecting it, and the other two decisions, using condoms and having sex.

Fig. 3b shows the second, older teen's beliefs. She, too, cites many factors, some seen as cutting both ways (\pm). She, too, cites some, but not all, of the factors in Fig. 2's expert model, as well as some factors outside it. The other 28 mental models show similarly complex and diverse views. The complexity is consistent with the moderately sophisticated decision-making processes that teens can

bring to bear on topics that interest them. The diversity in these mental models presumably reflects the diversity in what these teens have seen, heard, and experienced. Two quantitative measures of each teen's reports are the number of factors and the importance weights. These measures were not significantly different for teens older and younger than 16, consistent with other results showing older and younger teens responding similarly to open-ended questions about risk decisions (e.g., Beyth-Marom, Austin, Fischhoff, Palmgren, & Quadrel, 1993).

The complexity and variety of teens' thinking make it difficult to aggregate the views expressed in these interviews (understood more fully from the full transcripts). As a result, the interviews are best used to identify the beliefs held with any frequency and their intuitive formulation, providing the basis for a structured survey, posing standard questions to a larger sample. The next section reports such a survey.

Descriptive research: structured survey of belief prevalence

Method

Participants

One hundred and twenty-five adolescent females were recruited from local schools, after-school programs, and an on-line bulletin board (<http://pittsburgh.craigslislist.org/>), over a 5-month period. According to their self-reports, participants' ages ranged from 12 to 18 (mean = 16.1 years), 47% were Caucasian and 38% African-American, with 39% currently sexually active. Based on ZIP code, 80% were low income, defined as $\leq 200\%$ of the poverty level (= \$20,000 for a family of four, using US government guidelines).

Procedure

Participants completed paper (52%) or electronic (48%) surveys, taking about 15 min. The completion rate was 100% for paper and 78% for electronic. Participants received \$5 for completing the paper survey and the option of entering a lottery with a \$50 prize for completing the electronic survey. Those opting for the lottery provided an email address kept separate from their responses.

Based on the interviews and normative analyses, survey questions included possible influences on the three emergency contraceptive-related decisions, emergency contraceptive use, emergency contraceptive knowledge, and pregnancy risk for different contraceptive methods. We asked separately about decisions to have sex and not to have sex, following Beyth-Marom et al. (1993) and others who have found that complementary events can evoke different concerns. Questions were either multiple choice or open-ended. Some asked about respondents' personal experiences. Open-ended responses were coded independently by two individuals, with an inter-coder reliability correlation of 0.92.

Results

Analysis strategy

We report only those results directly relevant to FDA's expressed concerns: (1) teens' awareness of Plan B and

Table 1
Reasons cited for engaging in intercourse – or not

Reason	Percentage citing reasons	
	Under 16	16 and over
<i>To engage in intercourse</i>	<i>n = 41</i>	<i>n = 83</i>
Physical pleasure	27	52
Peer pressure	19	11
Partner retention	15	12
Partner pressure	17	7
Feeling ready ^a	15	7
Stress relief	7	8
Love ^a	7	8
Curiosity ^a	2	4
Alcohol	0	4
Hormones	2	2
Desire for pregnancy	0	1
Don't know	19	13
<i>To not engage in intercourse</i>	<i>n = 41</i>	<i>n = 84</i>
Pregnancy risk	73	70
STI risk	68	58
Just not ready	56	50
Parents finding out	34	29
Reputation	37	24
Religion	12	15
Physical discomfort	17	5
Haven't met the right person ^a	7	6
Too young ^a	5	4
Interferes with future goals ^a	5	1
Lack of partner trust ^a	2	1
No condom ^a	0	1
Don't know	7	5

^a Spontaneous response.

sexual experience were significantly more likely to cite pleasure (62% vs. 15%, $t(122) = 5.88$, $p < 0.001$), stress relief (13% vs. 2%, $t(122) = 2.21$, $p < 0.05$), and partner retention (21% vs. 2%, $t(122) = 3.27$, $p = 0.001$).

The bottom half of Table 1 shows the percentages of teens citing each factors as a reason *not* to have sex. The most common reasons were fear of pregnancy (71%) and STIs (60%), followed by not being ready (52%). Concern about parents finding out was cited by 30% and concern about reputation by 25%. The one age difference was that younger teens more frequently cited fear of physical discomfort (49% vs. 27%), $\chi^2(1, n = 124) = 6.824$, $p = 0.009$. Teens without experience more frequently cited not being ready (81% vs. 30%, $t(122) = 6.55$, $p < 0.001$) and religious beliefs (26% vs. 4%, $t(122) = 3.72$, $p < 0.001$).

Pregnancy and STI risks

Teens rated the importance of various factors in decisions to have sex, on a scale anchored at 1 = not important at all and 5 = very important. They gave the highest ratings to pregnancy (mean = 4.65) and STIs (mean = 4.58). Ratings for both pregnancy and STIs were significantly correlated with being sexually active ($r(117) = 0.217$, $p < 0.05$, and $r(117) = 0.244$, $p < 0.01$, respectively), indicating the greatest concern among those at greatest risk.

Although teens appear to know that pregnancy risk varies across the fertility cycle, most have inaccurate beliefs. They gave significantly higher probabilities of pregnancy, from a single act of intercourse, for 7–10 days before menstruation (luteal phase) than 7–10 days after

menstruation (follicular phase), (71% vs. 64%, $t(121) = 2.7$, $p = 0.008$). (These estimates were log-odds transformed to normalize the distributions.) Both estimates were significantly higher than those for menstrual phase (mean = 52%). Younger teens gave higher probabilities than did older ones for pregnancy from a single sexual act (median responses of 0.70 vs. 0.50, respectively) and from 10 sexual acts (median responses of 0.90 vs. 0.99). All these estimates are much higher than scientific ones (Tietze, 1960). The 10-act estimates are less than those implied by the one-act estimate (assuming independent events), replicating Linville, Fischer, & Fischhoff (1993).

There was only one statistically significant difference between older and younger teens' beliefs about the reliability of contraceptive methods (if used regularly): younger teens gave a lower probability to avoiding pregnancy with the patch (60.2% vs. 73.8%, $t(122) = 2.31$, $p < 0.05$). Assuming that their personal risk equals the population risk (as provided by Trussell, Koenig, Ellertson, & Stewart, 1997), teens overestimated the annual probability of pregnancy for all options: using condoms (25% vs. 16.6%), oral contraceptives (10% vs. 5.9%), withdrawal (75% vs. 22.5%), and no method (96.5% vs. 90%). As a result, they should overestimate the chances of needing Plan B. They greatly overestimated the probability of pregnancy for women who use Plan B (50% vs. 4.1%), thereby underestimating its value.

Plan B mechanism and timing

When asked how Plan B worked, 33% said that it prevented fertilization, 19% that it prevented a fertilized egg from growing, and 11% that it stopped ovulation – all three possibly being correct (Davidoff & Trussell, 2006). Others gave wrong answers, such as Plan B being a spermicide (12%), or did not know (26%). These beliefs were similar for teens who did and did not see abortion as immoral.

Teens' detailed comments in the interviews suggest that this disagreement about Plan B's mechanism is rooted in their confusion about the basic physiological processes of ovulation, fertilization, and implantation. Several teens described a process that they called "killing," but distinguished from abortion (e.g., "Does it kill the eggs? Maybe? When they're in your uterus. Or in your fallopian tube. Kills some eggs outside of ovaries, kills the sperm maybe. Kills something I'm guessing.").

Respondents' estimates of Plan B's effective period varied widely. While 18% chose 72 h, the longest period with near-maximum effectiveness, 10% cited 120 h, by which time Plan B is only moderately effective, and 40% cited 48 h or less, meaning that they might forgo it needlessly. Many (32%) were unsure. Only 58% said that they would "probably" or "definitely" have time to acquire Plan B, if needed.

Plan B concerns

Teens' importance ratings used a 6-point scale for paper surveys and a 7-point scale for the on-line survey. All were normalized to a 10-point scale. The most important factors in decisions about Plan B use were, in descending order, effectiveness (mean = 7.99), side effects (mean = 7.10), effects on future fertility (mean = 7.0), cost (mean = 5.86), partners'

desires (mean = 4.97), and religious reasons (mean = 4.87). There were two income differences: low-income participants placed less importance on future fertility, $\chi^2(6, n = 121) = 18.88, p = 0.004$, and side effects, $\chi^2(6, n = 121) = 25.37, p = 0.000$. There were no differences associated with age or sexual experience.

In the interviews, teens used terms like, “ [Teens are worried about] if it’s actually gonna work because they’re gonna be like terrified that they could be pregnant. And then they take it and they end up pregnant and they’re gonna be kind of mad about that.” And, “If [your parents] find out you took [Plan B], they’ll find out that you were pregnant. They’ll find out you had sex, and that’ll open a whole can of worms.” Those mentioning side effects did not always see them as serious, for example, “I don’t think [concern about side effects] would be that high because I think that in that situation the person would be more worried about the end result than what they had to go through, in order to not be pregnant.”

Among the 71 sexually experienced teens, 26 reported having had a condom break or unprotected sex, without subsequently using Plan B. Their most common reasons were the belief that they would not get pregnant ($n = 11$), fear that their parents would find out ($n = 8$), not getting around to it ($n = 8$), embarrassment at asking the doctor ($n = 8$), and inability to access a provider ($n = 8$). These responses were consistent with interview comments, expressing concern over lost privacy, if they discussed Plan B with anyone, including physicians who might tell their parents about their sexual activity.

Predictions regarding Plan B use

In terms of intentions to use Plan B after unprotected sex (or a condom break), 39% definitely would, 25% probably would, 17% maybe, 1% probably not, 3% would not, and 15% were unsure. These intentions did not differ by age, race, or income level. In a series of regression analyses, the importance rating for pregnancy risk and concerns was the only predictor of intention to use Plan B ($F(1, 101) = 9.249, p < 0.005$).

When asked how increased Plan B availability would affect their behavior, 45% of teens were unsure, while 35% said that it would not affect their willingness to have unprotected sex. When predicting others’ behavior, older and younger teens responded somewhat differently, $\chi^2(1, n = 124) = 8.55, p = 0.036$. Similar numbers thought that their peers would have more unprotected sex (45.8% older, 44% younger). Younger teens were more likely to predict that their peers would have less unprotected sex (15% vs. 4%). Older teens were more likely to predict no change in the rates of unprotected sex (29% vs. 12%). As expected, age and sexual experience were strongly correlated ($r(124) = 0.273, p < 0.01$), namely that teens who had more relevant experience predicted less change in sexual behavior.

We were also interested in teens’ opinions on the OTC policy. When asked who should be able to purchase Plan B without a prescription, 18% chose “anyone aged 12 and older,” 43% “anyone aged 16 and older,” 23% “anyone aged 18 and older” and 7% said no one. Teens with sexual experience were more likely to chose “anyone aged 12 and older” (28% vs. 4%), $\chi^2(1, n = 123) = 17.98, p = 0.001$.

Discussion

We present a behavioral decision research analysis of FDA’s ruling on over-the-counter status for Plan B. It begins with a normative analysis of three decisions, two central to FDA’s legal opinion, how availability will affect sexually active women’s decisions about (a) choice of contraceptive method and (b) whether to use Plan B if they suspect contraceptive failure (Fig. 1), and (c) a decision that is, arguably, outside FDA’s purview, whether to have sex. The normative analysis also includes a model of the processes affecting key elements of these decisions (Fig. 2). We then provide a descriptive account of how adolescent females view these decisions, based on 30 open-ended interviews and a structured survey allowing prevalence estimates for views expressed in the interviews, both structured around the normative analyses. The interviews and survey over-sampled high-risk teens, a population of particular interest to FDA.

Our specific results must be interpreted in the context of general research on adolescent decision-making competence. As noted above, that research finds that, by the mid-teen years, adolescents’ capabilities approach those of adults. However, teens’ knowledge varies by domain and, with it, their ability to make decisions in their own best interests. As mentioned, this cognitive account does not consider social and emotional pressures on decision making, beyond the supposition that greater cognitive mastery facilitates managing those pressures. Our results are further conditioned on the features of our (high-risk) sample and our reliance on self-reports (some of whose validity has been studied elsewhere).

Perhaps most directly relevant to FDA’s stated concerns, the interviews revealed no differences between younger (<16) and older teens, in terms of issues raised or opinions stated. Although the 30-interview sample should reveal only large differences, those would be the ones of the greatest policy relevance. The many age comparisons performed with the 125 surveys revealed four statistically significant differences: younger teens were (a) less likely to know about Plan B, (b) less likely to cite pleasure as a reason to have sex, (c) more likely to cite physical discomfort as a reason to avoid sex, and (d) more likely to think that greater availability would increase their peers’ unprotected sex (an expectation that did not apply to their own behavior). Thus, although FDA expressed concern about younger teens making Plan B their Plan A, our results find them much like older teens. The few differences suggest that they might actually be less impulsive (given their lower interest in physical pleasure and greater worry over physical discomfort), more concerned about their peers’ irresponsibility, and less likely to know enough about Plan B to count on using it. Sexual experience was more frequently a source of significant group differences than was age (although age and experience were obviously correlated), with more experienced teens perhaps learning by doing, perhaps more motivated to learn.

Thus, whatever reasoning led FDA to approve OTC availability for older teens should apply to younger teens as well – unless FDA is considering issues absent from our normative analysis and descriptive research. According to our results,

Plan B currently plays little role in teens' decisions about sex or contraceptive use. However, its availability does affect the ability to use Plan B, among those who would do so. Limited access to Plan B increases pregnancy risk, especially for those who underestimate how long they have to use it.

Whatever teens' access to Plan B, the research suggests three ways to help them make better choices about its use. (a) Some teens overestimate how long they have to take Plan B, possibly leading them to take unintended risks; some teens underestimate that time, possibly leading them to forego useful protection. The effective period should be an easy message to convey. (b) Some teens are unsure (or wrong) regarding Plan B's mechanism of action. Better information regarding Plan B's mechanism of action (including the scientific uncertainty) might help teens concerned about abortion to make appropriate choices. (c) Teens greatly underestimate Plan B's effectiveness, although those concerned about pregnancy risk would still use it. Given the centrality of pregnancy prevention in sexually active teens' decision making, seen here and elsewhere (Maticka-Tyndale, 1991; St. Lawrence, 1993), better information would help them use the Plan B option effectively.

Our interviews and survey are relatively intense, in terms of the depth and precision of the questions they ask about these personal topics. Such methods are needed to reveal the issues that teens consider relevant in their intuitive formulations. Indeed, an important result is that Plan B availability did not appear relevant to decisions about having sex and contraceptive use, while being central to decisions about its use.

As intense as they might be, these studies still elicit "cold" reports about "hot" behavior (Loewenstein, 1996). Speculatively, different predictions are possible, when extrapolating to actual decisions. One is that Plan B is so far removed from teens' decision making about sex and contraceptives that its availability will not affect their hot behavior, any more than it figured in their cold deliberations. A second is that when passions override teens' cold decisions about sex and contraceptives, leading to unprotected sex, they will act on plans for Plan B like those expressed here, in the "cold" morning after. Disciplining such speculations requires additional empirical research, toward which the present studies will, we hope, provide a useful step.

A final methodological question is the possibility that respondents misrepresented themselves, in order to create a good impression or satisfy researchers' expectations. The interviews sought to reduce this risk by (a) seeking a non-judgmental tone, (b) embedding Plan B questions in a broad discussion of sexual issues, and (c) asking about friends' and peer's behavior, rather than respondents' own. Although the survey asked about personal views and behaviors, it sought to maintain the same tone and embedding. The surveys used language from the interviews in order to convey sensitivity to respondents' perspectives. The variety of views expressed about Plan B suggests that respondents felt free to express themselves (or had different interpretations of what was socially desirable).

FDA's Plan B ruling prompted submission of some evidence and many opinions about teens' behavior. However, the ruling provided no clear picture of the decisions

being considered. Without such a picture, one cannot know which beliefs matter nor assess the adequacy of potential users' inevitably imperfect decision making. Our normative analyses sought to provide such clarity, regarding both the decisions (Fig. 1) and the processes determining their outcomes (Fig. 2). The descriptive studies focused on these decision-relevant issues, but without presuming that respondents conceptualized them as in the normative analyses. Interpreting the descriptive results in the context of the normative analyses allowed predicting the outcomes of various policies. Basing a ruling on such predictions would make its underlying philosophy relatively transparent, showing the patterns of expected behaviors and outcomes that regulators find acceptable.

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